

EXHIBIT C

Paul J. Michaels, M.D.

Page 1

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

)
IN RE: ETHICON, INC., PELVIC) Master File No.
REPAIR SYSTEM PRODUCTS)
PRODUCTS LIABILITY LITIGATION) 2:12-MD-02327
)
THIS DOCUMENT RELATES TO THE) MDL 2327
FOLLOWING CASES IN WAVE 2)
OF MDL 200:
)
Tamara Carter, et al. v.) JOSEPH R. GOODWIN
Ethicon, Inc., et al.) U.S. DISTRICT JUDGE
Civil Action No. 2:12-cv-01661)
)
Sandra Childress, et al. v.)
Ethicon, Inc., et al.) PAUL J. MICHAELS, M.D.
Civil Action No. 2:12-cv-01564)
) JUNE 18, 2016
Marion Chrysler v.)
Ethicon, Inc., et al.)
Civil Action No. 2:12-cv-02060)
)
Melissa Sanders, et al. v.)
Ethicon, Inc., et al.)
Civil Action No. 2:12-cv-01562)
)
Ana Sierra, et al. v.)
Ethicon, Inc., et al.)
Civil Action No. 2:12-cv-01819)
)
Toni Hernandez v.)
Ethicon, Inc., et al.)
Civil Action No. 2:12-cv-02073)
)

Reported by:

Rebecca J. Callow, CSR, RPR, CRR

Paul J. Michaels, M.D.

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| <p style="text-align: center;">Page 2</p> <p>1 2 DEPOSITION OF PAUL J. MICHAELS, M.D. 3 THIS DOCUMENT RELATES TO GENERAL TESTIMONY 4 Austin, Texas 5 Saturday, June 18th, 2016 6 8:04 a.m. 7 8 9 Deposition of PAUL J. MICHAELS, M.D., pursuant to 10 Notice held at the offices of Hissey Kientz, 11 9442 N. Capital of Texas Highway Building 1, 12 First Floor Conference Room, Austin, Texas, before 13 Rebecca J. Callow, Registered Merit Reporter, 14 Certified Realtime Reporter, Registered 15 Professional Reporter, and Notary Public in and 16 for the State of Texas. 17 18 19 20 21 22 23 24</p> | <p style="text-align: center;">Page 4</p> <p>1 A P P E A R A N C E S: 2 3 FOR JOHNSON & JOHNSON AND ETHICON, INC.: 4 Thomas Combs & Spann PLLC 5 300 Summers Street 6 Suite 1380 7 Charleston, West Virginia 25301 8 (304) 414-1807 9 BY: David B. Thomas, Esquire 10 dthomas@tcspllc.com 11 12 FOR JOHNSON & JOHNSON AND ETHICON, INC.: 13 Butler Snow, LLP 14 150 3rd Avenue South 15 Suite 1600 16 Nashville Tennessee 37201 17 (615) 651-6700 18 BY: M. Andrew Snowden, Esquire 19 andy.snowden@butlersnow.com 20 21 22 23 24</p> |
| <p style="text-align: center;">Page 3</p> <p>1 A P P E A R A N C E S: 2 3 FOR PLAINTIFFS: 4 Aylstock, Witkin, Kreis & Overholtz, PLLC 5 17 East Main Street 6 Suite 200 7 Pensacola, Florida 32502 8 (850) 202-1010 9 BY: Bryan F. Aylstock, Esquire 10 baylstock@awkolaw.com 11 12 FOR PLAINTIFFS: 13 Danny L. Curtis, P.C. 14 9229 Ward Parkway 15 Suite 370 16 Kansas City, Missouri 64114 17 (816) 523-4667 18 BY: Danny L. Curtis, Esquire 19 dcurtis@dannylcurtispc.com 20 21 22 23 24</p> | <p style="text-align: center;">Page 5</p> <p>1 INDEX 2 PAGE 3 PAUL J. MICHAELS, M.D. 4 Examination by Mr. Thomas 6 5 Changes and corrections 127 6 Signature Page 129 7 Court Reporter's Certificate 130 8 9 10 11 EXHIBITS 12 NO. DESCRIPTION PAGE 13 Exhibit 1 Notice of Deposition of Paul 7 14 Michaels. M.D. 15 Exhibit 2 Flash drive containing reliance 8 16 materials of Paul Michaels, 17 M.D. 18 Exhibit 3 Expert Report of Paul T. 16 19 Michaels, M.D. (Re: Sandra 20 Childress) 21 Exhibit 4 Exhibit D: Reliance List for 17 22 Paul Michaels, M.D. 23 24</p> |

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| <p>1 (Witness sworn.)</p> <p>2 MR. AYLSTOCK: Before we get started,</p> <p>3 Dave, I guess, I know there were some e-mails flying</p> <p>4 back and forth. To the extent that Dr. Michaels was</p> <p>5 withdrawn as a general expert, he's -- by my e-mails</p> <p>6 for cases where he's designated, our understanding</p> <p>7 is that he will be designated both as case-specific</p> <p>8 and generic in those and we're permitting you to</p> <p>9 take a generic general deposition of Dr. Michaels</p> <p>10 pursuant to the notices that you provided.</p> <p>11 MR. THOMAS: Thank you.</p> <p>12 PAUL J. MICHAELS, M.D.,</p> <p>13 Called as a witness herein, having been</p> <p>14 previously duly sworn by a Notary Public, was</p> <p>15 examined and testified as follows:</p> <p>16 EXAMINATION</p> <p>17 BY MR. THOMAS:</p> <p>18 Q. Good morning, Doctor.</p> <p>19 A. Good morning.</p> <p>20 Q. I introduced myself to you before the</p> <p>21 deposition. My name is David Thomas and I represent</p> <p>22 Ethicon.</p> <p>23 You've given depositions before?</p> <p>24 A. Yes.</p> | <p>1 MR. THOMAS: Okay. And is that all</p> <p>2 the information that you produced pursuant to the</p> <p>3 notice of deposition?</p> <p>4 MR. CURTIS: It's all that I produced.</p> <p>5 I think that there are other materials that have</p> <p>6 also been produced, but that's an explanation of why</p> <p>7 Dr. Michaels did not bring materials in paper copy</p> <p>8 this morning.</p> <p>9 MR. THOMAS: Thank you.</p> <p>10 A. I have a flash drive that has my CV and all</p> <p>11 the representative information that was included in</p> <p>12 Schedule A of this notice of deposition.</p> <p>13 BY MR. THOMAS:</p> <p>14 Q. Can I have that flash drive?</p> <p>15 A. Yes.</p> <p>16 (Exhibit 2 marked.)</p> <p>17 MR. THOMAS: I've marked as</p> <p>18 Exhibit No. 2 the flash drive that Dr. Michaels just</p> <p>19 gave me.</p> <p>20 BY MR. THOMAS:</p> <p>21 Q. Without going into great detail, unless you</p> <p>22 can, is there anything on the Schedule A that you</p> <p>23 did not produce?</p> <p>24 MR. AYLSTOCK: Just again to</p> |
| Page 7 | Page 9 |
| <p>1 (Exhibit 1 marked.)</p> <p>2 BY MR. THOMAS:</p> <p>3 Q. Let me show you what I've marked as</p> <p>4 Deposition Exhibit No. 1. It's a notice of</p> <p>5 deposition for you in six cases in the pelvic mesh</p> <p>6 MDL.</p> <p>7 Have you seen that notice of deposition</p> <p>8 before?</p> <p>9 A. Yes.</p> <p>10 Q. Did you bring anything with you in response</p> <p>11 to Schedule A attached to the notice?</p> <p>12 MR. CURTIS: Doctor, before you</p> <p>13 answer, for the record, we filed written</p> <p>14 objections -- e-filed written objections to the</p> <p>15 documents listed in the attachment to the notice for</p> <p>16 his deposition in all of these cases. I didn't</p> <p>17 bring written objections to be made an exhibit,</p> <p>18 Mr. Thomas, but I wanted the record to include that.</p> <p>19 And also, we provided, by electronic</p> <p>20 link, the documents that were on the reliance list</p> <p>21 for each of the cases to include the medical</p> <p>22 records, the deposition transcripts, and other</p> <p>23 materials provided the doctor. So you have those in</p> <p>24 that form.</p> | <p>1 reiterate, we objected to form to a large portion of</p> <p>2 it --</p> <p>3 MR. THOMAS: I understand. I don't</p> <p>4 want to spend my time going through each one of them</p> <p>5 to figure it out.</p> <p>6 MR. AYLSTOCK: That's fine.</p> <p>7 BY MR. THOMAS:</p> <p>8 Q. And if there's something that you know of</p> <p>9 that you didn't produce, tell me. Otherwise, we'll</p> <p>10 get to it later.</p> <p>11 A. Not that I'm exactly aware of.</p> <p>12 Q. Okay. And that's fine. We'll figure that</p> <p>13 out, perhaps, as we go along.</p> <p>14 Would you state your full name for the</p> <p>15 record, please?</p> <p>16 A. Paul Joseph Michaels.</p> <p>17 Q. And, Dr. Michaels, you are a medical</p> <p>18 doctor?</p> <p>19 A. Yes.</p> <p>20 Q. And what is your area of specialty?</p> <p>21 A. Pathology. Specifically atomic and</p> <p>22 clinical pathology with a subspecialty in</p> <p>23 cytopathology.</p> <p>24 Q. Have you been identified as an expert</p> |

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| <p>1 witness in the Ethicon Pelvic Repair System Products 2 Liability Litigation?</p> <p>3 A. Yes.</p> <p>4 Q. And you're here to testify on behalf of the 5 plaintiffs?</p> <p>6 A. Yes.</p> <p>7 Q. In six cases.</p> <p>8 Who contacted you about this 9 litigation?</p> <p>10 A. I don't remember exactly the order of how I 11 was contacted, but I believe it was Mr. Aylstock's 12 firm.</p> <p>13 Q. Okay. And what were you asked to do?</p> <p>14 A. I was asked to serve as an expert with 15 regards to the pathologic evaluation of the mesh 16 specimens in these clients that had brought this 17 lawsuit.</p> <p>18 Q. The notice of deposition lists six cases in 19 which you're prepared to give opinions in this MDL. 20 Did you review other cases?</p> <p>21 A. Yes.</p> <p>22 Q. How many other cases did you review?</p> <p>23 A. One or two.</p> <p>24 Q. Okay. And did you decline to give opinions</p> | <p>1 more light to you off the record, yes, I would tell 2 him not to answer that question.</p> <p>3 MR. THOMAS: Okay. Again, I don't 4 want to spend time discussing stuff. That's going 5 to waste my time or we're not going to get any 6 answers.</p> <p>7 BY MR. THOMAS:</p> <p>8 Q. Prior to your retention in this case, can 9 you tell me something about your familiarity with 10 pelvic mesh implants?</p> <p>11 A. Well, as a pathologist, I've been exposed 12 to these specimens over the last several years. So 13 I've grossly examined them, microscopically examined 14 them, prior to being involved in this litigation, 15 and that was basically it.</p> <p>16 Q. Has that been in your capacity as a 17 pathologist associated with the hospital?</p> <p>18 A. That's correct.</p> <p>19 Q. And how many pelvic mesh explants have you 20 as a pathologist analyzed prior to your retention in 21 this litigation?</p> <p>22 A. I would probably say somewhere around two 23 dozen, maybe.</p> <p>24 Q. Over what period of time?</p> |
| Page 11 | Page 13 |
| <p>1 in those cases?</p> <p>2 A. No.</p> <p>3 One of them I did give an opinion. I 4 just -- it's not on here. I think it's for later.</p> <p>5 And then the other one I was told kind 6 of halfway through that that I shouldn't work on the 7 case anymore. I don't know what was happening to 8 it, if they were withdrawing or settling. I didn't 9 ask. I was just told on this case -- and I don't 10 even remember the name -- don't work anymore on it.</p> <p>11 Q. Do you know the names of the plaintiffs in 12 those two cases?</p> <p>13 MR. AYLSTOCK: And with regard to 14 that, I'm going to object to the extent that he may 15 have been a consulting expert on those cases, you're 16 not entitled to know the names of those cases until 17 the time -- such time as he's been disclosed as an 18 expert in those.</p> <p>19 MR. THOMAS: I can't know that, Bryan. 20 Are you instructing him not to answer or what? I 21 don't know.</p> <p>22 MR. AYLSTOCK: With regard -- one of 23 those cases is not mine, so for that, without his 24 lawyer here, who -- and I can probably shed some</p> | <p>1 A. Seven, eight years, maybe.</p> <p>2 Q. Do you recall any time where you as a 3 pathologist have been asked to analyze pelvic mesh 4 implants to determine the extent to which the mesh 5 contributed to the pathology in the tissue that you 6 analyzed?</p> <p>7 A. Could you repeat that?</p> <p>8 MR. THOMAS: Could you? 9 (The record was read as requested: 10 "Do you recall any time where you as a 11 pathologist have been asked to analyze 12 pelvic mesh implants to determine the 13 extent to which the mesh contributed 14 to the pathology in the tissue that 15 you analyzed?")</p> <p>16 A. Well, I would say that as a pathologist, 17 that's what you do on a day-to-day basis. Whether 18 you're specifically asked by the submitting surgeon, 19 a particular clinical question, that's what we do is 20 analyze specimens and report their pathological 21 significance.</p> <p>22 So I would say that -- yes, that's 23 part of my purview as a pathologist just with 24 general specimens would be to answer those clinical</p> |

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| <p>1 questions, whether they're specifically asked or 2 not.</p> <p>3 BY MR. THOMAS:</p> <p>4 Q. Prior to your retention in this litigation, 5 have you written pathology reports which expressed 6 opinions about the impact that the presence of 7 polypropylene mesh may have played in the pathology 8 of the tissue that you reviewed?</p> <p>9 A. Well, with regards to impact, I would say 10 if you were talking about a foreign body response, 11 that is in relationship to the mesh, then yes.</p> <p>12 Q. Anything other than commenting on the 13 foreign body response due to the presence of the 14 mesh?</p> <p>15 A. Fibrosis, fat necrosis. Those are the main 16 things that we address in pathology reports with 17 regards to either mesh or any foreign-type material.</p> <p>18 Q. Have you had any training prior to your 19 work in this litigation concerning the impact of 20 polypropylene mesh in tissue?</p> <p>21 A. I wouldn't say I've had any specific 22 training with regards to the polypropylene mesh in 23 tissue and its reaction. But just as a general 24 pathologist, within our training we are, I guess,</p> | <p>1 provided to me or when I did my own PubMed search 2 with regards to mesh, polypropylene, transvaginal 3 surgeries, et cetera, I came across a lot of 4 articles that way. I read a lot of articles in that 5 respect.</p> <p>6 I was -- I asked for and was given 7 some of the internal Ethicon documents with respect 8 to the litigation and their research on mesh.</p> <p>9 And I reviewed some depositions from 10 different physicians that had been involved in the 11 litigation prior to me being asked to be in the 12 litigation, as well as some of their prior expert 13 reports to get a general overview of some of the 14 issues in the litigation. I would say those would 15 be the main things.</p> <p>16 Q. What prior expert reports did you review?</p> <p>17 A. Reports I think by physicians 18 Klausterhoven, Clinge, I believe, Iakovlev as well.</p> <p>19 Q. Any other expert reports you recall 20 reviewing?</p> <p>21 A. Well, not in the beginning, no. 22 (Exhibit 3 marked.)</p> <p>23 BY MR. THOMAS:</p> <p>24 Q. Let me show you what's Deposition Exhibit</p> |
| Page 15 | Page 17 |
| <p>1 taught and schooled with respect to foreign bodies 2 in general.</p> <p>3 Q. Have you ever authored any papers related 4 to the impact of polypropylene mesh on tissue in the 5 pelvic floor?</p> <p>6 A. No, I have not.</p> <p>7 Q. Have you ever conducted any research 8 concerning the impact of polypropylene mesh on 9 tissue in the pelvic floor?</p> <p>10 A. No.</p> <p>11 Q. Have you ever spoken or taught on the topic 12 of the issue of the impact of polypropylene mesh on 13 tissue in the pelvic floor?</p> <p>14 A. No.</p> <p>15 Q. When you were asked to assist the 16 plaintiffs in this litigation, what did you do to 17 prepare yourself for the work that you were going to 18 do?</p> <p>19 A. Well, I re-reviewed a lot of the general 20 pathology of inflammation and foreign body 21 granulomas reactions from several different 22 textbooks and, I guess, online pathology sources.</p> <p>23 I reviewed a lot of the literature 24 that I came into contact with, either that was</p> | <p>1 No. 3, which is your expert report in the Childress 2 case. The expert report in the Childress case has a 3 heading, "Background," "Summary of Opinions," and 4 "Comment."</p> <p>5 I'm interested now in the Comment 6 section of Exhibit No. 3.</p> <p>7 Does the Comment section in 8 Exhibit No. 3, which goes from pages 2 through 5, 9 does that generally represent your general report in 10 this case?</p> <p>11 A. I would say that that generally represents 12 my general opinions with regards to the case, yes.</p> <p>13 Q. Okay. And without showing you the other 14 five reports, does -- can I use the Childress report 15 as a template for your general opinions across all 16 six cases?</p> <p>17 A. I don't know about that, because I -- they 18 change -- I can't remember specifically, as I sit 19 here, but -- and without comparing all of the 20 reports to one another, there may be some 21 differences from one report to another to this 22 comment section.</p> <p>23 Q. Okay. 24 (Exhibit 4 marked.)</p> |

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| <p style="text-align: right;">Page 18</p> <p>1 BY MR. THOMAS:</p> <p>2 Q. Let me show you what's been marked as</p> <p>3 Deposition Exhibit No. 4.</p> <p>4 Deposition Exhibit No. 4 is Exhibit D</p> <p>5 that I was provided Thursday afternoon and</p> <p>6 represented to be your reliance list in connection</p> <p>7 with your opinions in this case.</p> <p>8 A. I don't think so, because this one says</p> <p>9 "Chrysler deposition" on page 5, and we're talking</p> <p>10 about Childress.</p> <p>11 Q. Well, the reason why I say that -- well,</p> <p>12 this was given to me by plaintiffs on Thursday</p> <p>13 afternoon.</p> <p>14 Other than the page 5, which are</p> <p>15 individual medical records I think you said for the</p> <p>16 Chrysler case, do the first four pages of that</p> <p>17 Exhibit No. 4 represent your reliance materials for</p> <p>18 your general opinions in the case?</p> <p>19 A. I believe so, yes.</p> <p>20 Q. And you said a minute ago that you obtained</p> <p>21 these materials from a variety of sources.</p> <p>22 Do you know which of these literature</p> <p>23 references you obtained on your own?</p> <p>24 A. I couldn't go through them and pick them</p> | <p style="text-align: right;">Page 20</p> <p>1 A. Well, for general pathology, background</p> <p>2 information with regards to maybe some of the later</p> <p>3 advancements with regards to inflammatory cytokines</p> <p>4 and mechanisms that maybe were even more recent than</p> <p>5 the most recent textbooks I have on the subject, but</p> <p>6 not much in addition to that.</p> <p>7 Q. And what did you search for specifically in</p> <p>8 your Internet research?</p> <p>9 A. Inflammation mechanisms, foreign body</p> <p>10 response, pathology foreign body response,</p> <p>11 histology, biology, et cetera.</p> <p>12 Q. You mentioned that you studied papers</p> <p>13 related to the complications associated with mesh in</p> <p>14 the pelvic floor.</p> <p>15 Why was that important to you?</p> <p>16 A. Because as part of my role as an expert, I</p> <p>17 am correlating the findings based on the literature</p> <p>18 with respect to histopathologic features that I'm</p> <p>19 finding in the mesh explants.</p> <p>20 So if there are studies done with</p> <p>21 respect to correlating these findings, it was</p> <p>22 important to me, as a pathologist reviewing the</p> <p>23 mesh, to be able to identify those and correlate</p> <p>24 them with the individual case-specific opinions, I</p> |
| <p style="text-align: right;">Page 19</p> <p>1 out.</p> <p>2 Q. Counsel supplied you selected literature?</p> <p>3 A. Initially, yes.</p> <p>4 Q. Are you able to identify from materials</p> <p>5 that you have in your files those materials that</p> <p>6 counsel provided to you?</p> <p>7 A. No. Because I put them all in one general</p> <p>8 folder.</p> <p>9 Q. And likewise, are you able to identify</p> <p>10 those materials that you found on your own through</p> <p>11 your own PubMed search?</p> <p>12 A. No.</p> <p>13 Q. I believe you said you did some Internet</p> <p>14 research.</p> <p>15 A. Well, with regards to general -- I mean,</p> <p>16 PubMed is an Internet research, so yes, I did.</p> <p>17 Q. Did you do any -- what did you search for</p> <p>18 under PubMed?</p> <p>19 A. Transvaginal mesh, you know, mesh pain,</p> <p>20 mesh complications, a variety of different -- I</p> <p>21 mean ...</p> <p>22 Q. Other than your PubMed search on the</p> <p>23 Internet, did you conduct any other Internet</p> <p>24 research?</p> | <p style="text-align: right;">Page 21</p> <p>1 guess.</p> <p>2 Q. In analyzing the complications associated</p> <p>3 with the use of mesh in the pelvic floor, did you</p> <p>4 determine the rate of those complications in</p> <p>5 surgeries?</p> <p>6 A. From what I read, the rates seemed quite</p> <p>7 variable from study to study.</p> <p>8 And it would depend on what you were</p> <p>9 specifically looking at and what was really</p> <p>10 considered a complication, because that seems to</p> <p>11 also have changed with respect to how, for example,</p> <p>12 recurrence is classified.</p> <p>13 Q. To the extent that you studied the rates of</p> <p>14 complications occurring from mesh in the pelvic</p> <p>15 floor, did you include those papers in your reliance</p> <p>16 list, which is Exhibit 4?</p> <p>17 A. I included everything in my reliance list</p> <p>18 that I thought was pertinent to my opinions and that</p> <p>19 I felt like seemed to be a pertinent study.</p> <p>20 Q. Are the rates of complications from the use</p> <p>21 of mesh in the pelvic floor pertinent to your</p> <p>22 opinions in the case?</p> <p>23 MR. AYLSTOCK: Object to the form of</p> <p>24 the question to the extent that you're talking about</p> |

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| <p>1 mesh generally.</p> <p>2 THE WITNESS: Can you repeat that</p> <p>3 question?</p> <p>4 (The record was read as requested:</p> <p>5 "Are the rates of complications from</p> <p>6 the use of mesh in the pelvic floor</p> <p>7 pertinent to your opinions in the</p> <p>8 case?"")</p> <p>9 A. I don't think necessarily.</p> <p>10 BY MR. THOMAS:</p> <p>11 Q. Why do you say you don't think necessarily?</p> <p>12 A. Well, I'm just -- because these are all --</p> <p>13 I'm being involved in cases where the complication</p> <p>14 has occurred. So whether that occurs in 1 in 10,000</p> <p>15 or 1 in 5, it doesn't matter. It occurred in this</p> <p>16 case.</p> <p>17 So, although it's something that is a</p> <p>18 background information with respect to how common</p> <p>19 something is, I don't think in a particular case it</p> <p>20 changes any opinion that I would render.</p> <p>21 Q. As a part of your work in this case, did</p> <p>22 you undertake to determine how complications which</p> <p>23 result from the use of mesh in the pelvic floor</p> <p>24 occur?</p> | <p>1 A. Oh, okay. Yes.</p> <p>2 Q. So you did seek to understand the</p> <p>3 complications that occur for the treatment of</p> <p>4 conditions in the pelvic floor that don't involve</p> <p>5 mesh?</p> <p>6 A. Well, in many of the reports that I had,</p> <p>7 there were discussions regarding comparing the</p> <p>8 complications with mesh from complications of</p> <p>9 surgeries that were similar prior to or without the</p> <p>10 use of synthetic mesh.</p> <p>11 Q. As a part of your work in this case, did</p> <p>12 you make a determination of whether complications</p> <p>13 were greater or fewer in surgeries using mesh for</p> <p>14 the treatment of stress urinary incontinence as</p> <p>15 opposed to procedures involving the</p> <p>16 Burch colposuspension?</p> <p>17 A. Well, with respect to mesh versus non-mesh,</p> <p>18 yes.</p> <p>19 Q. And what did you learn from your work?</p> <p>20 A. That the complications from surgeries with</p> <p>21 respect to using synthetic mesh were greater.</p> <p>22 Q. Is that for the treatment of stress urinary</p> <p>23 incontinence?</p> <p>24 A. Well, I would say, in general, with respect</p> |
| Page 23 | Page 25 |
| <p>1 THE WITNESS: Could you repeat that?</p> <p>2 Sorry.</p> <p>3 THE REPORTER: No problem.</p> <p>4 (The record was read as requested:</p> <p>5 "As a part of your work in this case,</p> <p>6 did you undertake to determine how</p> <p>7 complications which result from the</p> <p>8 use of mesh in the pelvic floor</p> <p>9 occur?"")</p> <p>10 A. Yes.</p> <p>11 BY MR. THOMAS:</p> <p>12 Q. And how did you do that?</p> <p>13 A. By trying to read some of the literature</p> <p>14 regarding the complications.</p> <p>15 Q. And did you seek to understand the risk of</p> <p>16 complications in the pelvic floor from non-mesh</p> <p>17 procedures?</p> <p>18 A. I don't know what non-mesh procedures</p> <p>19 you're talking about.</p> <p>20 Q. Do you know what a Burch colposuspension</p> <p>21 is?</p> <p>22 A. So you mean -- so you mean general</p> <p>23 treatment for prolapse, et cetera, that's not mesh?</p> <p>24 Q. Correct.</p> | <p>1 to organ prolapse and stress urinary incontinence,</p> <p>2 my understanding from reviewing the literature is</p> <p>3 that the use of synthetic mesh resulted in an</p> <p>4 increased number of complications with respect to</p> <p>5 those types of surgical procedures compared to</p> <p>6 procedures where non-synthetic mesh was used.</p> <p>7 Q. Okay. Specifically, did your review of the</p> <p>8 literature lead you to conclude that the risk of</p> <p>9 complications in the use of mesh for the treatment</p> <p>10 of stress urinary incontinence is greater than the</p> <p>11 risk of complications from non-mesh procedures used</p> <p>12 to treat stress urinary incontinence?</p> <p>13 A. I would say my general opinion, as I sit</p> <p>14 here now, from what I recall would be yes. But I</p> <p>15 don't have a lot of those studies in front of me to</p> <p>16 look at their reported complication rates.</p> <p>17 Q. Do you remember which studies you used in</p> <p>18 that regard?</p> <p>19 A. With respect to the authors' names?</p> <p>20 Q. Yes. Anything you can do to identify the</p> <p>21 study so I can find it.</p> <p>22 A. I can go through my reliance list one by</p> <p>23 one.</p> <p>24 Q. I don't want to do that. I'm just asking</p> |

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| <p>1 if you recall anything off the top of your head. 2 A. Well, for me to identify these number of 3 studies, I would have to go through them because I 4 reviewed so much literature in preparation for -- 5 Q. I understand. 6 A. Okay. 7 Q. Do you agree that acute or chronic 8 dyspareunia is a risk of non-mesh surgery of the 9 pelvic floor? 10 MR. AYLSTOCK: Objection to form. 11 THE WITNESS: Could you repeat that? 12 (The record was read as requested: 13 "Do you agree that acute or chronic 14 dyspareunia is a risk of non-mesh 15 surgery of the pelvic floor?") 16 A. I would say it can be, yes. 17 BY MR. THOMAS: 18 Q. Do you agree that acute or chronic pain is 19 a risk of non-mesh surgery in the pelvic floor? 20 MR. AYLSTOCK: Objection to form. 21 A. Acute or chronic pain, in general, or ... 22 BY MR. THOMAS: 23 Q. Yes. 24 A. Like in your head? Pain can be anywhere,</p> | <p>1 floor? 2 A. I would say that vaginal scarring is a 3 potential risk. 4 Q. And do you agree that infection is a 5 potential risk of non-mesh surgery in the pelvic 6 floor? 7 A. Yes. I would say that infection is a risk 8 of basically any surgery regardless of where it's 9 at. 10 Q. And do you agree that urinary problems, be 11 it urinary frequency, urgency, dysuria, retention, 12 obstruction or incontinence, is a risk of non-mesh 13 surgery in the pelvic floor? 14 THE WITNESS: I'm sorry. Could you 15 repeat that? 16 MR. AYLSTOCK: Objection. Form. 17 (The record was read as requested: 18 "And do you agree that urinary 19 problems, be it urinary frequency, 20 urgency, dysuria, retention, 21 obstruction or incontinence, a risk of 22 non-mesh surgery in the pelvic 23 floor?") 24 MR. AYLSTOCK: Objection. Form.</p> |
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| <p>1 so I don't -- that seems like a nonspecific 2 question. I don't understand it. 3 Q. What I'm trying to understand is when a 4 person has surgery in the pelvic floor for the 5 treatment of stress urinary incontinence or pelvic 6 organ prolapse whether acute or chronic pain is a 7 potential risk from that surgery. 8 A. You can repeat the question all you want. 9 But what I'm saying is, pain where? 10 Pain can occur anywhere in your body, 11 so if you're going to ask me if pain is a 12 complication of something, I need to know if you're 13 talking about pain in a particular location. 14 Q. I'm sorry. I'll ask a better question. 15 Do you agree that acute or chronic pain 16 in the pelvic -- strike that. 17 Do you agree that acute or chronic pain 18 in the pelvic floor is a risk of non-mesh surgery for 19 the treatment of pelvic organ prolapse and stress 20 urinary incontinence in the pelvic floor? 21 A. Yes. I would say pain in the pelvic floor 22 can be a risk. 23 Q. Do you agree that vaginal scarring is a 24 potential risk of non-mesh surgery in the pelvic</p> | <p>1 A. I would agree that urinary problems can be 2 a potential risk of surgery in the pelvic floor. 3 BY MR. THOMAS: 4 Q. Do you agree that organ or nerve damage are 5 potential risks of surgery in the pelvic floor? 6 MR. AYLSTOCK: Objection to form. 7 A. I would want to know what organs you're 8 talking about that would be dysfunctional. 9 BY MR. THOMAS: 10 Q. Are there risks of injury to any organs in 11 pelvic floor surgery? 12 A. I would say organs that are in that 13 anatomic location. 14 Q. And the same with respect to nerves that 15 are in that anatomic location. 16 A. Correct. Nerves that are in that anatomic 17 location can potentially be injured during the 18 surgery. 19 Q. Bleeding is a potential risk of non-mesh 20 surgery in the pelvic floor? 21 MR. AYLSTOCK: Objection to form. 22 A. Bleeding is a risk for any surgery 23 regardless of location. 24 ///</p> |

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| <p>1 BY MR. THOMAS:</p> <p>2 Q. Inflammation is a risk of non-mesh surgery 3 in the pelvic floor?</p> <p>4 MR. AYLSTOCK: Objection to form.</p> <p>5 A. Inflammation is a general process, it's not 6 really a risk.</p> <p>7 BY MR. THOMAS:</p> <p>8 Q. Inflammation happens in connection with 9 non-mesh surgery in the pelvic floor. Do you agree 10 with that?</p> <p>11 A. Inflammation is a very broad subject. So 12 whether you're talking about transient inflammation 13 or acute inflammation or granulomatous inflammation, 14 it's a very general term.</p> <p>15 Q. All three of those that you just used are 16 risks of surgery -- risks of surgery for non-mesh 17 surgery in the pelvic floor, aren't they?</p> <p>18 MR. AYLSTOCK: Objection. Form.</p> <p>19 A. I do not think so. You don't have a 20 foreign body granulomatous inflammatory response if 21 you're not using a foreign body.</p> <p>22 BY MR. THOMAS:</p> <p>23 Q. To the extent there's sutures involved in 24 this surgery, it's a foreign body.</p> | <p>1 MR. AYLSTOCK: Objection to form.</p> <p>2 A. I would say they can be.</p> <p>3 BY MR. THOMAS:</p> <p>4 Q. And are neuromuscular problems in the 5 abdominal area a potential risk of non-mesh surgery 6 in the pelvic floor?</p> <p>7 MR. AYLSTOCK: Objection to form.</p> <p>8 A. I would say maybe the lower abdominal area 9 it would be a potential risk.</p> <p>10 BY MR. THOMAS:</p> <p>11 Q. And is there a risk of one or more 12 surgeries to treat an adverse event in non-mesh 13 surgery in the pelvic floor?</p> <p>14 MR. AYLSTOCK: Objection to form.</p> <p>15 A. I would say that's a general risk of any 16 surgery.</p> <p>17 BY MR. THOMAS:</p> <p>18 Q. And is there a risk of recurrence or 19 failure in non-mesh surgery in the pelvic floor?</p> <p>20 MR. AYLSTOCK: Objection to form.</p> <p>21 THE WITNESS: Could you repeat that? (The record was read as requested: "And is there a risk of recurrence or failure in non-mesh surgery in the</p> |
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| <p>1 A. Well, sutures can be absorbable or 2 nonabsorbable.</p> <p>3 So if they're nonabsorbable, yes. If 4 they're absorbable, once they're gone, no.</p> <p>5 Q. Okay. Is fistula formation a risk of 6 non-mesh surgery in the pelvic floor?</p> <p>7 A. I would think that fistula formation could 8 be a potential risk for non-mesh surgery in the 9 pelvic floor.</p> <p>10 Q. Are neuromuscular problems a risk of 11 surgery -- non-mesh surgery in the pelvic floor?</p> <p>12 MR. AYLSTOCK: Objection to form.</p> <p>13 A. I don't know what kind of neuromuscular 14 problems you're referring to.</p> <p>15 BY MR. THOMAS:</p> <p>16 Q. Are neuromuscular problems in the pelvic 17 floor muscles a risk of non-mesh surgery in the 18 pelvic floor?</p> <p>19 MR. AYLSTOCK: Same objection.</p> <p>20 A. I would say they can be a potential risk.</p> <p>21 BY MR. THOMAS:</p> <p>22 Q. Are neuromuscular problems in the lower 23 extremities a potential risk for non-mesh surgery of 24 the pelvic floor?</p> | <p>1 pelvic floor?"</p> <p>2 A. Recurrence or failure of what?</p> <p>3 BY MR. THOMAS:</p> <p>4 Q. Whatever condition is being treated.</p> <p>5 A. I would say that's a potential risk.</p> <p>6 Q. And in non-mesh surgery in the pelvic floor 7 using sutures or grafts. There's a potential risk 8 of a foreign body response. Would you agree with 9 that?</p> <p>10 MR. AYLSTOCK: Objection to form.</p> <p>11 A. What kind of grafts?</p> <p>12 BY MR. THOMAS:</p> <p>13 Q. Any foreign body that you're putting in -- 14 into the body.</p> <p>15 A. Is it biological or synthetic?</p> <p>16 Q. Well, let's start with synthetic.</p> <p>17 A. Well, synthetic, yes.</p> <p>18 Q. What about biological? Is there a risk of 19 a foreign body response to a biological graft?</p> <p>20 A. I guess it would depend on the type of graft.</p> <p>21 Q. And for the use of sutures and grafts in 22 non-mesh surgery in the pelvic floor, is there a 23 risk of erosion of those sutures or grafts?</p> |

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| <p>1 MR. AYLSTOCK: Objection to form. 2 Completely vague. 3 A. It would depend on the exact type of 4 surgery and where those grafts or sutures are. 5 BY MR. THOMAS: 6 Q. Is there a risk of contraction of or 7 shrinkage of tissues in non-mesh surgery involving 8 the pelvic floor? 9 MR. AYLSTOCK: Objection to form. 10 A. Well, with respect to scars, you can have a 11 contracture of a scar. I guess it just is different 12 with respect to quality and quantity of the 13 contracture. 14 BY MR. THOMAS: 15 Q. Let's go to Exhibit 3, please. In 16 Exhibit No. 3 you discuss the issue related to pore 17 size in mesh. Fair? 18 A. I would say in very vague terms, yes. 19 Q. What did you know about issues related to 20 pore size before your work in this case? 21 A. Very little general information. 22 Q. What did you know before your work in this 23 case? 24 A. That pore size varied based on the mesh.</p> | <p>1 pores should be? 2 A. I didn't specifically pay attention to 3 numbers with respect to pore sizes. 4 Q. But, do you, as you sit here today, have an 5 opinion about how large the pore needs to be so that 6 these issues that you just identified with the pore 7 size don't occur? 8 A. I just said that I don't have any specifics 9 with regards to the numbers, the sizes of the pores. 10 Q. No matter what the size of the pore, in 11 your opinion, is there still a risk of the issues 12 you just described from the use of any mesh for the 13 treatment of conditions in the pelvic floor? 14 MR. AYLSTOCK: Objection to form. 15 A. Well, I would say with regards to that 16 question the keyword would be "any." So there could 17 be any risk, it's just depending on the amount. 18 BY MR. THOMAS: 19 Q. What do you look for in pathology for 20 evidence that pores in the mesh are causing a 21 complication? 22 A. Well, under the microscope I would look at 23 the tissue between the filaments which represents 24 the pores, or the filament spaces which would</p> |
| <p style="text-align: center;">Page 35</p> <p>1 Q. Is that all you knew before your work in 2 this case? 3 MR. AYLSTOCK: Objection to form. 4 A. And that there were differences with them. 5 But I didn't know specific differences until I 6 started reading the literature with respect to this 7 litigation. 8 BY MR. THOMAS: 9 Q. Okay. After you began your work on this 10 litigation and you reviewed the litigation -- 11 reviewed the literature, what is the problem with 12 pore size? What is the issue? 13 A. Well, I would say the main issue, from my 14 point of view as a pathologist, is that the smaller 15 the pore size, the less likely you can have adipose 16 tissue infiltrate into those pores between the 17 filaments, and so there's much more likely to have 18 bridging fibrosis between the filaments which will 19 make the mesh less pliable, firmer, and also create 20 a microenvironment where it's basically a 21 constricting compartment-type syndrome with respect 22 to the tissue that's able to infiltrate and 23 incorporate within the pores. 24 Q. Do you have an opinion about how large the</p> | <p style="text-align: center;">Page 37</p> <p>1 represent the pores, and see what kind of tissue is 2 between those and associated with those. 3 Q. What kind of tissue do you want to see to 4 show that there are no complications? 5 MR. AYLSTOCK: Objection to form. 6 THE WITNESS: Could you repeat that? 7 THE REPORTER: Yes. 8 (The record was read as requested: 9 "What kind of tissue do you want to 10 see to show that there are no 11 complications?") 12 A. I don't think there would be any tissue 13 that would confirm that there are zero 14 complications. 15 BY MR. THOMAS: 16 Q. Okay. Let me ask this question. I 17 probably asked a bad question. 18 What tissue are you looking for to 19 identify any risk of complications from pore size? 20 MR. AYLSTOCK: Objection to form. 21 A. Well, again, I would say if I'm looking at 22 the tissue and the mesh, that there's a problem with 23 the mesh. There was a problem that was identified 24 by the clinician with that mesh, depending on the</p> |

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| <p>1 clinical scenario, of course, and this isn't an 2 autopsy and I'm looking at mesh. 3 So I would say features that would be 4 most commonly associated with better incorporation 5 of mesh would be seeing abundant adipose tissue in 6 between the filaments which would indicate that 7 there would maybe be possibly less constriction 8 within those pores.</p> <p>9 THE WITNESS: Can we get some more 10 water?</p> <p>11 MR. AYLSTOCK: Sure.</p> <p>12 MR. THOMAS: There's a refrigerator 13 full of it.</p> <p>14 MR. AYLSTOCK: And any time you want 15 to take a break.</p> <p>16 THE WITNESS: I'm fine.</p> <p>17 (Pause in proceedings.)</p> <p>18 THE WITNESS: All right. Thank you.</p> <p>19 BY MR. THOMAS:</p> <p>20 Q. In your general report, Exhibit No. 3, you 21 also discussed issues of the weight of the mesh. 22 What is your criticism about the weight 23 of mesh?</p> <p>24 MR. AYLSTOCK: You mean page number 3?</p> | <p>1 condition. It's more of a consequence or a finding 2 where based on typically scar formation, you have a 3 contracture or compression or shrinking, so to 4 speak, of tissue where it comes together, is firm 5 and, I guess, less mobile.</p> <p>6 Q. Again, is this an issue that you learned 7 from the literature or an issue that you learned 8 about from your own experience?</p> <p>9 A. About contracture in mesh? Or contracture 10 in general?</p> <p>11 Q. Contracture in mesh.</p> <p>12 A. Well, I would say both. I would say my 13 experience as a pathologist when I've examined mesh 14 as a day-to-day workload issue, you can see that 15 it's not normal mesh and that it's crinkled and 16 contracted, irregular, deformed. I would say all of 17 those would correspond to that finding or 18 consequence of contracture.</p> <p>19 Q. Every time that you've looked at mesh in 20 your work as a pathologist, has it been in a 21 histopathological slide?</p> <p>22 A. No.</p> <p>23 MR. AYLSTOCK: Objection to form.</p> |
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| <p>1 MR. THOMAS: Page 3, Exhibit 3.</p> <p>2 A. Well, as I stated, mesh that has a lighter 3 weight has better tissue integration with less 4 inflammation and scar formation, and is more likely 5 to remain more pliable over time than a 6 heavier-weight mesh.</p> <p>7 BY MR. THOMAS:</p> <p>8 Q. Are those statements in your report that 9 you just referred to, are those based on your review 10 of the literature or based upon your own experience?</p> <p>11 A. Based on my review of the literature.</p> <p>12 Q. You've not done a comparative study of 13 different weight meshes to see how they perform in 14 the pelvic floor. Is that fair?</p> <p>15 A. That's correct. I have not done my own 16 study.</p> <p>17 Q. And you've not done any kind of study on 18 your own to determine how different pore sizes 19 perform in the pelvic floor. Is that correct?</p> <p>20 A. That's correct.</p> <p>21 Q. You also discuss in your report the risk of 22 a condition known as contracture. What is 23 contracture?</p> <p>24 A. I don't know if I would call it a</p> | <p>1 BY MR. THOMAS: 2 Q. Have you looked at any mesh other than mesh 3 that had already been affixed in formalin? 4 A. Yes. 5 Q. Have you looked at pelvic floor explants -- 6 analyzed pelvic floor explants before they've been 7 fixed in formalin?</p> <p>8 MR. AYLSTOCK: Objection to form.</p> <p>9 A. Grossly, yes.</p> <p>10 BY MR. THOMAS: 11 Q. Okay. And under what circumstances would 12 you, as a pathologist, look at pelvic floor explants 13 before they've been fixed in formalin?</p> <p>14 A. When it comes from the surgeon and we 15 examine it grossly before formalin's been added.</p> <p>16 Q. You told me before that you think about 17 over the last seven or eight years you've maybe 18 looked at about two dozen pelvic floor mesh 19 explants. How many times have those mesh explants 20 been delivered to you without being placed in 21 formalin?</p> <p>22 MR. AYLSTOCK: Objection to form.</p> <p>23 A. I don't know. I would say maybe half of 24 the times that I initially examined them and then</p> |

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| <p>1 added the formalin to the container. 2 BY MR. THOMAS: 3 Q. Do you agree that when mesh that's been 4 implanted in the pelvic floor is removed from the 5 body that the tissues surrounding the mesh contract? 6 MR. AYLSTOCK: Objection to form. 7 A. I don't understand that question. 8 BY MR. THOMAS: 9 Q. Okay. You understand that when mesh is 10 implanted in the pelvic floor that the tissue grows 11 in through the pores of the mesh and -- grows 12 through the pores of the mesh? 13 A. Yes. 14 Q. And then when mesh is removed, when the 15 tissue and the elastins in the tissue are released 16 from the body, that the mesh itself with the tissue 17 then contracts before it's placed in formalin. Do 18 you agree with that? 19 MR. AYLSTOCK: Objection to form. 20 A. I don't know that I would use the word 21 "contract" in that -- I guess -- 22 I guess I could say that it changes 23 shape or maybe is deformed. But when I am thinking 24 of -- when we're discussing contracture, I'm</p> | <p>1 Q. And you understand that formalin fixation 2 will cause excised tissue to contract due to the 3 cross-linking of the proteins and the collagen? 4 MR. AYLSTOCK: Objection to form. 5 A. I haven't specifically read those details 6 about mesh and formalin fixation and, quote/unquote, 7 "contracting." 8 BY MR. THOMAS: 9 Q. Do you have reason to disagree with that 10 statement? 11 A. Well, I would have to see the data and the 12 studies that have -- the biochemical studies. I'm 13 not, you know, a polymer scientist, so I don't have 14 all those studies off the top of my head. 15 Q. As a part of your work in this case, have 16 you analyzed how various meshes are implanted in the 17 body? 18 A. I would say generally speaking. 19 Q. And how did you familiarize yourself with 20 the mesh implantation process? 21 A. I watched some videos. I know from my own 22 experience as a physician, both in medical school 23 and doing internships, I've witnessed some of these 24 types of procedures during urology.</p> |
| <p style="text-align: center;">Page 43</p> <p>1 thinking more of the pathophysiologic fibrosis that 2 draws the tissue together. But does it change shape 3 after its out of the body artificially based on the 4 circumstances that it was in both in vivo and then 5 outside? Yes. 6 BY MR. THOMAS: 7 Q. Okay. And why does that happen? 8 A. Well, that happens with almost any type of 9 specimen, that when you remove it, there is a change 10 in the way the tissue is laying, in the way the 11 tissue is shaped. And it's because in the body 12 when -- before a particular type of tissue, whatever 13 it is, is removed, it's within a structural 14 framework. And once you remove that structural 15 framework, there are natural consequences to taking 16 that out and it no longer looks the same as when it 17 was in the body. 18 Q. And when you then take the explant and 19 place it in formalin, you understand that formalin 20 reacts with the proteins on the mesh to fix the 21 specimen. 22 A. The proteins that are in the tissue, the 23 tissue changes predominantly, and that's with any 24 tissue in formalin, yes.</p> | <p style="text-align: center;">Page 45</p> <p>1 I would say kind of over the years I 2 have had different experiences that have 3 familiarized myself with those types of surgical 4 procedures. 5 Q. Do you remember the videos you watched? 6 A. I don't remember the specific videos. 7 Q. I didn't see them on your reliance list. 8 A. Well, I didn't also put my urology rotation 9 in medical school on my reliance list, but that's -- 10 Q. But you've reviewed these videos in 11 connection with your work in this case, didn't you? 12 MR. CURTIS: Objection. Let him 13 answer. 14 A. Yeah. 15 So no. In the past -- I would say in 16 the past and in connection with this case, there are 17 several different types of experiences that I've had 18 that have formed my, I guess, familiarity with the 19 procedures. 20 BY MR. THOMAS: 21 Q. Have you familiarized yourself with the 22 mesh removal process? 23 A. I would say that mesh is removed in 24 different ways, so I don't know if there is an exact</p> |

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| <p>1 process of how a mesh, from one patient to another, 2 is removed.</p> <p>3 Q. Fair enough.</p> <p>4 Have you made any attempt to study the 5 different ways that mesh may be explanted from the 6 pelvic floor?</p> <p>7 A. I don't really understand that question. 8 That's like -- I don't understand that question.</p> <p>9 Q. What don't you understand?</p> <p>10 A. Well, it's like asking me have I studied 11 the ways that I can walk from point A to point B.</p> <p>12 It depends on how mesh is removed; it 13 depends on where it is in the body, and what vital 14 structures it's next to. And if it's eroded into 15 the rectum, has it eroded into the vagina? Has it 16 eroded into the urethra? Has it eroded into the 17 bladder? Has it ruptured a vessel?</p> <p>18 I mean, how it will be removed 19 surgically, even though I'm not a surgeon, it's 20 clear that it would be completely based on the 21 anatomic location that mesh had eroded into.</p> <p>22 Q. In connection with your work on the six 23 cases for which you've given opinions in this 24 litigation, have you studied the methodology used by</p> | <p>1 A. Well, we want others to do them; not that I 2 allow them.</p> <p>3 Q. Why do you want others to do them?</p> <p>4 A. Because that's what they do for a living 5 and my focus is diagnostics.</p> <p>6 Q. Have you studied the effect of the slide 7 preparation process on the polypropylene mesh in the 8 slides that you looked at in this litigation?</p> <p>9 A. I reviewed some studies that addressed both 10 polypropylene material being -- maybe changes that 11 occurred, or that were thought to have occurred 12 because of the processing, and then other studies 13 that looked at the polypropylene without any sort of 14 processing. I've looked at, I think, both of those 15 types of studies.</p> <p>16 Q. Are those peer-reviewed studies or are 17 those expert opinion reports?</p> <p>18 A. I thought they were peer-reviewed studies.</p> <p>19 Q. Would those studies be in your reliance 20 list, Exhibit No. 4?</p> <p>21 A. I don't know. I think so, maybe.</p> <p>22 Q. Okay. And do you recall what you concluded 23 from your review of the studies about any impact 24 that the slide preparation process may have on the</p> |
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| <p>1 the surgeon to remove the mesh?</p> <p>2 A. Well, I read the operative reports.</p> <p>3 Q. Anything else?</p> <p>4 A. Not that I can recall, other than reading 5 the operative reports that were associated with the 6 procedures.</p> <p>7 Q. Doctor, do you consider yourself 8 knowledgeable about the pathology slide preparation 9 process?</p> <p>10 A. I would say I have a general knowledge, but 11 I don't participate in that as a pathologist.</p> <p>12 Q. Have you ever, yourself, processed 13 histology slides from pathology?</p> <p>14 A. Processed in what respect?</p> <p>15 Q. Put the tissue in a paraffin block.</p> <p>16 A. I've put the tissue in the block and then I 17 have loaded the cassettes in the past into the 18 processor and taken them out, but I've never 19 actually inserted the paraffin into the block once 20 the tissue has been finally processed.</p> <p>21 Q. Do you do the microtoming?</p> <p>22 A. I have in the past.</p> <p>23 Q. Is that something you typically allow 24 others to do now?</p> | <p>1 polypropylene that you analyzed in connection with 2 these cases?</p> <p>3 A. Well, my conclusion was that, based on what 4 I was seeing and what you see in general under light 5 microscopy, with regards to the characteristics of 6 the polypropylene that it was not significantly 7 influenced based on the processing.</p> <p>8 Q. I believe you just told me it was based on 9 your review of the slides. What I'm interested --</p> <p>10 A. And the literature.</p> <p>11 Q. And what I'm interested in is what did the 12 literature tell you about the impact of the slide 13 preparation process on the polypropylene that you 14 were looking at in connection with these cases?</p> <p>15 MR. AYLSTOCK: Objection to form. I 16 think he's already answered that.</p> <p>17 A. When I form an opinion it's based on 18 everything, it's not based on just one thing. So I 19 don't remember what I was specifically thinking when 20 I was just looking at one or a couple of studies.</p> <p>21 But my general opinion with regards to that subject 22 is what I just said.</p> <p>23 BY MR. THOMAS:</p> <p>24 Q. Okay. And when you say it's not</p> |

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| <p>1 significantly affected, do you have any opinions it 2 affected at all?</p> <p>3 MR. AYLSTOCK: Objection to form.</p> <p>4 A. Well, I think the slide processing in 5 pathology in general is, you know, a process that 6 has gone on for years, and we know that it changes 7 everything. It changes DNA, RNA, proteins; it 8 changes antigen retrieval. But what is important is 9 if there's any substantive changes to the tissues.</p> <p>10 So, for example, if I'm looking at a 11 breast cancer and it's been in formalin for a day, 12 does that change the proteins of that cancer that it 13 expresses? Yes. Does it change it to the respect 14 that it would impact anything negatively or change 15 anything in a clinically significant way? No.</p> <p>16 And I would say the same thing with 17 any type of tissue or synthetic material, that, you 18 know, does the processing maybe change something at 19 a molecular or biochemical level. I would imagine 20 that it would. There's different chemicals that are 21 being exposed to it, but does it make it look one 22 way versus another? No. I would say, no.</p> <p>23 BY MR. THOMAS:</p> <p>24 Q. Does the microtoming process make the</p> | <p>1 that fair?</p> <p>2 A. Yes. I would say that's fair. We take all 3 of that into consideration.</p> <p>4 Q. Prior to your work in this case, had you 5 read anywhere that as polypropylene mesh degraded 6 in vivo?</p> <p>7 A. You said "mesh"?</p> <p>8 Q. Yes.</p> <p>9 A. I don't recall seeing anything or having 10 remembered reading anything about mesh, in general, 11 that's derived from polypropylene, but suture 12 material, yes.</p> <p>13 Q. And when you talk about suture material, 14 are you talking about polypropylene suture material?</p> <p>15 A. Well, in general, yes.</p> <p>16 I would say I've read about different 17 types of both absorbable and nonabsorbable suture 18 material and other types of material that can be 19 implanted and how it degrades.</p> <p>20 Q. Prior to your work in this case, what was 21 your knowledge about Prolene mesh or sutures 22 degrading in the body?</p> <p>23 MR. AYLSTOCK: Objection to form.</p> <p>24 A. Prolene, you mean like with a capital "P,"</p> |
| <p style="text-align: center;">Page 51</p> <p>1 appearance of the tissue change from the way it was 2 in vivo to the way it is under the slide?</p> <p>3 MR. AYLSTOCK: Objection to form.</p> <p>4 A. I would say the microtoming process can. 5 But usually, as a pathologist, you can identify when 6 there are folds in the tissue as opposed to 7 something that is occurring biologically or 8 pathologically.</p> <p>9 BY MR. THOMAS:</p> <p>10 Q. There are artifacts that can occur in the 11 microtoming process that pathologists can detect.</p> <p>12 A. That was a statement; are you asking a 13 question?</p> <p>14 Q. Yes.</p> <p>15 Is that true?</p> <p>16 A. So yes. In any type of specimen, there are 17 artifacts that we can see and are comfortable 18 usually identifying that are artifacts of the 19 microtoming process and of the fixation process and 20 of the staining process.</p> <p>21 Q. Each one of those three is capable of 22 producing artifacts, and it's the job of the 23 pathologist to identify those artifacts and take 24 those into consideration with your analysis. Is</p> | <p style="text-align: center;">Page 53</p> <p>1 Prolene, from polypropylene or ...</p> <p>2 BY MR. THOMAS:</p> <p>3 Q. Correct. Prolene --</p> <p>4 Did you know that "Prolene" is the 5 brand name for Ethicon's polypropylene?</p> <p>6 A. Yes. That's why I was clarifying.</p> <p>7 I don't specifically remember seeing 8 the brand name.</p> <p>9 Q. What about polypropylene, generally? What 10 is your recollection before this litigation about 11 your knowledge of polypropylene mesh or sutures 12 degrading in the body?</p> <p>13 A. That the sutures can. That was before this 14 litigation that they can degrade.</p> <p>15 Q. In what context?</p> <p>16 A. In what context "what"?</p> <p>17 How does it happen?</p> <p>18 Q. What do you remember that you read that the 19 polypropylene sutures degraded?</p> <p>20 A. I didn't read about -- I don't remember 21 reading about the biochemical consequences or 22 mechanisms, just that it can.</p> <p>23 From a pathologist's point of view 24 with respect to recognizing changes in the tissue,</p> |

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| <p>1 because we not infrequently will see suture material 2 in all types of excisions.</p> <p>3 Q. Prior to your work in this case, have you 4 ever analyzed polypropylene mesh to determine the 5 extent to which it may have degraded in the body?</p> <p>6 A. No. I don't recall having done that 7 before.</p> <p>8 Q. Prior to your work in this case, have you 9 ever analyzed polypropylene sutures to determine the 10 extent to which they may have degraded in the body?</p> <p>11 A. I would say I haven't analyzed them with 12 respect to extent, just known that it occurs -- can 13 occur after a period of time and will have seen 14 suture material microscopically, but not more than 15 that.</p> <p>16 Q. And those times that you've just described, 17 is that in connection with your work as a 18 pathologist?</p> <p>19 A. Yes.</p> <p>20 Q. And do you remember the specifics of those 21 circumstances where you recall seeing polypropylene 22 sutures degrade?</p> <p>23 A. They were in the setting of a prior 24 abdominal surgery, from my recollection, and it was</p> | <p>1 be the mechanisms of this degradation 2 over time?"</p> <p>3 MR. AYLSTOCK: Same objection.</p> <p>4 A. I don't know if I've specifically studied 5 that. I mean, there have been probably basic 6 general discussions about biologic mechanisms that 7 contribute to degradation of foreign material in 8 general, but I wouldn't say that I specifically 9 analyzed those.</p> <p>10 BY MR. THOMAS:</p> <p>11 Q. If you go to page 5 of Exhibit No. 3.</p> <p>12 A. Okay.</p> <p>13 Q. And the paragraph beginning "Finally," you 14 talk about degradation.</p> <p>15 These are all -- strike that.</p> <p>16 The papers and the documents that are 17 listed in that paragraph, are those things that you 18 reviewed in connection with your work in this 19 litigation specifically. Is that fair?</p> <p>20 A. They're some of them, yes.</p> <p>21 Q. Okay. But there's nothing in paragraph -- 22 in that paragraph that you had reviewed and read 23 prior to the time of your work in this litigation. 24 Is that fair?</p> |
| Page 55 | Page 57 |
| <p>1 a re-excision of a tumor that had recurred. And 2 there was a discussion in the past about -- this is 3 more of an academic discussion about focusing on the 4 suture material and the types of foreign body 5 responses and what to look for as a pathologist, and 6 what can be associated with them, et cetera.</p> <p>7 Q. What conclusions did you reach about the 8 use of polypropylene sutures in the body following 9 that experience as a pathologist?</p> <p>10 A. I wouldn't say there were any dramatic 11 conclusions, just that it could degrade over time.</p> <p>12 Q. And other than your work in this case, have 13 you studied what are alleged to be the mechanisms of 14 this degradation over time?</p> <p>15 MR. AYLSTOCK: Objection to form.</p> <p>16 A. With this case? Or litigation?</p> <p>17 BY MR. THOMAS:</p> <p>18 Q. Litigation.</p> <p>19 A. Oh.</p> <p>20 THE WITNESS: Can you repeat that?</p> <p>21 THE REPORTER: Yes.</p> <p>22 (The record was read as requested: 23 "And other than your work in this case 24 have you studied what are alleged to</p> | <p>1 MR. AYLSTOCK: Objection to form.</p> <p>2 A. Let me read the paragraph.</p> <p>3 BY MR. THOMAS:</p> <p>4 Q. I'm referring to the studies in the Ethicon 5 documents themselves.</p> <p>6 A. You're referring to what?</p> <p>7 Q. Let me ask the question again, Doctor. I'm 8 trying to make it simple.</p> <p>9 In this paragraph on page 5 you list a 10 number of papers. Correct?</p> <p>11 A. Yes.</p> <p>12 Q. Those papers were supplied to you by 13 counsel as a part of your work in this litigation.</p> <p>14 A. I don't know if all the papers were.</p> <p>15 Q. Do you recall seeing any of those papers 16 prior to your work in this litigation?</p> <p>17 MR. CURTIS: I apologize. I'm 18 confused. Are you talking about the Ethicon-only 19 documents?</p> <p>20 MR. THOMAS: I'm talking about the 21 papers now. I haven't talked about the Ethicon 22 documents yet.</p> <p>23 MR. CURTIS: All right.</p> <p>24 A. I don't recall.</p> |

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| <p>1 BY MR. THOMAS:</p> <p>2 Q. Okay. What is the clinical significance of 3 the degradation that you describe in paragraph -- in 4 that paragraph on page 5 of the report?</p> <p>5 MR. AYLSTOCK: Are you talking about 6 the "Finally" paragraph?</p> <p>7 MR. THOMAS: I'm talking about 8 degradations.</p> <p>9 BY MR. THOMAS:</p> <p>10 Q. But let me ask it this way: 11 What is the clinical significance of 12 what you describe as degradation in your report?</p> <p>13 A. I would say the clinical significance with 14 respect to degradation is that once you're degrading 15 a foreign body and it breaks apart, there's a 16 greater surface area now to that foreign body that's 17 in connection and in affiliation with the tissue. 18 So that would increase the inflammatory response, 19 because now you have new foreign antigens that are 20 in, I guess, direct contact with the tissue.</p> <p>21 That would then increase the 22 inflammatory response, and that increased 23 inflammatory response would potentially or likely, 24 given the severity of it, lead to additional damage</p> | <p>1 A. Well, that would be, I guess, the 2 pathological features which would correlate with 3 other clinical symptoms.</p> <p>4 Q. Okay. Let me ask it this way, then: 5 Is it fair to understand from your 6 perspective as a pathologist that the significance of 7 the degradation to you would be an increased 8 inflammatory response and increased scarring?</p> <p>9 A. I would say those would be the main things, 10 yes.</p> <p>11 Q. And however those manifested themselves in 12 patients would be another issue?</p> <p>13 A. Correct.</p> <p>14 Q. All right. Are you aware of any scientific 15 study published anywhere that describes the clinical 16 significance that you've just related to 17 degradation?</p> <p>18 A. I've seen it described. It's not like I 19 just made that up. So yeah. I have. I just -- I 20 don't know -- I wouldn't know who's the author.</p> <p>21 Q. Okay. Did you know this information or 22 have this opinion prior to your work in this case?</p> <p>23 A. Well, I would have that general opinion, 24 but I hadn't specifically studied it prior to this</p> |
| <p style="text-align: center;">Page 59</p> <p>1 to the remaining polypropylene or foreign material. 2 And then that would then lead to more breakdown and 3 more degradation, which would then turn into this, 4 you know, basically cyclical phenomenon where you 5 have a feedback loop that's just constantly going, 6 contributing, to greater amounts of inflammation and 7 scarring.</p> <p>8 Q. Have you finished?</p> <p>9 A. Yes.</p> <p>10 Q. Okay. Can I limit the clinical 11 significance that you identify from the degradation 12 process that you describe to be an increased 13 inflammatory response and increased scarring?</p> <p>14 MR. AYLSTOCK: Objection to form.</p> <p>15 BY MR. THOMAS:</p> <p>16 Q. Those are the two things you just told me, 17 I think.</p> <p>18 A. Well, I said a whole paragraph, so ...</p> <p>19 Q. I know. I was listening carefully. I 20 thought you described each time those things: 21 Increased inflammatory response, due to the cyclical 22 nature of it, and then increased scarring because of 23 the increased inflammatory response.</p> <p>24 Is there anything else?</p> | <p style="text-align: center;">Page 61</p> <p>1 case in the depth that I have, no.</p> <p>2 Q. What is your knowledge of the extent to 3 which -- strike that.</p> <p>4 What is your opinion about the extent 5 to which mesh implanted in the pelvic floor degrades? 6 Is there a limit to it?</p> <p>7 MR. AYLSTOCK: Objection to form.</p> <p>8 THE WITNESS: Could you repeat that?</p> <p>9 I'm sorry.</p> <p>10 THE REPORTER: Yes. (The record was read as requested: 11 "What is your opinion about the extent 12 to which mesh implanted in the pelvic 13 floor degrades? Is there a limit to 14 it?")</p> <p>15 MR. AYLSTOCK: Same objection.</p> <p>16 MR. CURTIS: Yeah. I'm sorry. I just 17 don't understand the question. Go ahead.</p> <p>18 A. Me neither. Yeah. 19 I would have to -- I don't understand 20 what you mean by "a limit," so I don't understand 21 the question.</p> <p>22 BY MR. THOMAS:</p> <p>23 Q. Okay. You've read Dr. Iakovlev's report.</p> |
| | 16 (Pages 58 to 61) |

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| 1 | Correct? | 1 the -- I've studied it in the sense that I have |
| 2 | A. Some of them. | 2 examined it myself. So I would say, by definition, |
| 3 | Q. You know Dr. Iakovlev said that the outer | 3 I'm studying it. |
| 4 | core of polypropylene mesh degrades and then it | 4 But with respect to the extent, I |
| 5 | stops. Do you know that? | 5 haven't done a comparison study with regards to |
| 6 | MR. AYLSTOCK: Objection to form. | 6 other types of synthetic material and their |
| 7 | A. I don't specifically recall those words. | 7 embrittlement. |
| 8 | BY MR. THOMAS: | 8 BY MR. THOMAS: |
| 9 | Q. Do you have any opinions suggesting that | 9 Q. Is it fair to say that the opinions that |
| 10 | the degradation that you've studied and describe in | 10 you have with respect to embrittlement and crack |
| 11 | your report on page 5 stops after a certain period | 11 formation, based on work that you've done yourself, |
| 12 | of time? | 12 is your work in these cases? |
| 13 | MR. CURTIS: I don't know if it makes | 13 A. No. |
| 14 | a difference. You repeatedly refer to that | 14 Q. What other work have you done to study the |
| 15 | section -- "Comment" section in Exhibit 3 as his | 15 embrittlement and crack formation on |
| 16 | general report. I think his testimony was those | 16 Prolene polypropylene? |
| 17 | pages contained his general opinions, not that it's | 17 A. Well, the embrittlement is by my own |
| 18 | his general report. That's a distinction he made. | 18 examination of the gross specimens in the past. I |
| 19 | MR. THOMAS: I'm not worried about | 19 didn't examine any of these specimens grossly. |
| 20 | that. If you want to make that distinction, that's | 20 So when I've -- you know, my |
| 21 | up to you. | 21 experience, I guess, as a pathologist and a |
| 22 | MR. CURTIS: No, no. I just want to | 22 physician outside of the context of this litigation |
| 23 | make sure that when we're finished with the process, | 23 is -- is we've already discussed there are a couple |
| 24 | we all understand what you were after. | 24 of dozen cases where I've seen the mesh myself, and |
| | Page 63 | Page 65 |
| 1 | BY MR. THOMAS: | 1 examined it, both in the context of prior to |
| 2 | Q. Is it your opinion that degraded mesh | 2 formalin fixation and after formalin fixation. And |
| 3 | becomes brittle? | 3 when I've examined those, those have been very stiff |
| 4 | A. Yes. | 4 and rigid and sharp, and I would say that that |
| 5 | Q. Is it your opinion that degraded mesh forms | 5 contributes to my knowledge of that process. |
| 6 | cracks on the surface? | 6 Now, whether I've actually looked at |
| 7 | A. Yes. | 7 them, you know, biochemically, no, I haven't. But, |
| 8 | Q. And is it your opinion that degraded mesh | 8 you know, studying them, I would say that my |
| 9 | loses mechanical properties? | 9 experience in the past would be characteristic of |
| 10 | A. Yes. I would say all those are both my | 10 studying the material. |
| 11 | opinions and the opinions of the general medical | 11 Q. Do you have available for us to analyze the |
| 12 | literature. | 12 pathology samples that you looked at over the past |
| 13 | Q. Have you ever studied the extent to which | 13 seven or eight years where you've reached these |
| 14 | Prolene polypropylene becomes brittle over time? | 14 conclusions? |
| 15 | MR. AYLSTOCK: Objection to form. | 15 A. No. |
| 16 | Suture? | 16 Q. Do you have pathology reports for those two |
| 17 | A. I don't ... | 17 dozen or so times where you had the opportunity to |
| 18 | THE WITNESS: Could you repeat that? | 18 analyze explants from the pelvic floor? |
| 19 | THE REPORTER: Yes. | 19 A. I don't have them myself, no. |
| 20 | (The record was read as requested: | 20 Q. The last thing you say is the |
| 21 | "Have you ever studied the extent to | 21 polypropylene -- excuse me -- that polypropylene |
| 22 | which Prolene polypropylene becomes | 22 loses mechanical properties. What mechanical |
| 23 | brittle over time?" | 23 properties are you referring to there? |
| 24 | A. Well, I would say with regards to study | 24 MR. AYLSTOCK: Where are you at? |

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|---|---|
| <p>1 MR. THOMAS: Right in the middle of 2 the paragraph. "... embrittlement, crack formation, 3 and loss of mechanical properties."</p> <p>4 A. I would have to re-review that Clave 5 article.</p> <p>6 BY MR. THOMAS:</p> <p>7 Q. Okay. As you sit here today, you don't 8 know what mechanical properties?</p> <p>9 A. Well, no. I'm using that as a general 10 term, but not the specific mechanical properties 11 other than their ability to perhaps be functional.</p> <p>12 Q. Are you relying on the work of others to 13 support your opinion that polypropylene that goes 14 through a degradation process loses mechanical 15 properties.</p> <p>16 A. Not entirely, no.</p> <p>17 Q. And what is your own experience that allows 18 you to offer that opinion?</p> <p>19 A. Well, because I have felt and know what the 20 mesh feels like and functions like before it's 21 implanted. I have felt it before and I've also felt 22 it as a pathologist when it's come out of the 23 patient. And it's in some of these cases that I 24 have been aware of -- obviously, I don't examine all</p> | <p>1 cetera?</p> <p>2 So over time, I've become somewhat 3 familiar with the different types even before this 4 litigation. So that's why I said I would say most 5 of them, but I didn't do a particular count.</p> <p>6 Q. So to the extent that degradation 7 associated with a mesh implant is causing clinical 8 significance you would expect to find increased 9 inflammation around that degradation. Is that fair?</p> <p>10 MR. AYLSTOCK: Objection to form.</p> <p>11 A. I would expect to see inflammation.</p> <p>12 Correct.</p> <p>13 MR. AYLSTOCK: Dave, whenever you're 14 at a good point, I could use a bathroom break.</p> <p>15 MR. THOMAS: Let's take a break.</p> <p>16 (Recess from 9:31 a.m. to 9:40 a.m.)</p> <p>17 BY MR. THOMAS:</p> <p>18 Q. Doctor, you told me earlier that you 19 reviewed some information from Dr. Iakovlev.</p> <p>20 A. Yes.</p> <p>21 Q. Did you review expert reports from 22 Dr. Iakovlev?</p> <p>23 A. Yes.</p> <p>24 Q. How many?</p> |
| Page 67 | Page 69 |
| <p>1 of these patients that don't have the mesh removed, 2 and maybe some of them it stays relatively pliable. 3 I don't know the extent.</p> <p>4 But in the ones that I have examined, 5 they are hard and don't move very much, and I would 6 say that that is reflective of the fact that their 7 physical and mechanical properties have been 8 altered.</p> <p>9 Q. Do you know which of the meshes that you've 10 held in your hands following explant before fixation 11 in formalin were Prolene meshes?</p> <p>12 A. I would say, from my understanding, most of 13 them were. But I don't know the percentage.</p> <p>14 Q. And why do you say most of them were?</p> <p>15 A. Because when I have these gross specimens 16 with synthetic material or any type of foreign 17 material, I make a habit of reviewing the operative 18 reports to correlate what I'm seeing and what I'm 19 not seeing, what I'm not submitting for 20 histopathologic evaluation.</p> <p>21 So in these operative reports they 22 will discuss, this is this type, this is this type. 23 You know, this is, whatever, Boston Scientific. You 24 know, whether it's an implant for breast implant, et</p> | <p>1 A. One or two maybe.</p> <p>2 Q. Did you review any depositions of 3 Dr. Iakovlev?</p> <p>4 A. Yes.</p> <p>5 Q. How many?</p> <p>6 A. I think two.</p> <p>7 Q. Did you review any other documents from 8 Dr. Iakovlev?</p> <p>9 A. Just articles that he's published in the 10 peer-reviewed literature.</p> <p>11 Q. Do you still have the depositions that you 12 reviewed of Dr. Iakovlev?</p> <p>13 A. I would imagine they're on that flash 14 drive.</p> <p>15 Q. Okay. And do you still have the studies 16 that you reviewed of Dr. Iakovlev?</p> <p>17 A. Yes. Same thing. They're on the flash 18 drive.</p> <p>19 Q. They're not on your exhibit list or your 20 reliance list. That's why I asked the question.</p> <p>21 A. Oh, well, some of it I've gotten since I 22 submitted my reports.</p> <p>23 Q. We got an updated one Thursday.</p> <p>24 A. An updated what?</p> |

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| <p>1 Q. Reliance list, Thursday. 2 A. I don't know. 3 Q. What have you gotten since you've submitted 4 your reports that you've reviewed in connection with 5 your work in this case? 6 A. Some of the client deposition transcripts. 7 Q. "Client" as in plaintiff deposition 8 transcripts? 9 A. Yeah. Sorry. The plaintiff. 10 Q. We each have different clients. 11 A. Right. Sorry. 12 The -- some of the plaintiff 13 deposition transcripts. 14 I've reviewed some of the defense 15 expert reports. 16 I've reviewed probably some additional 17 medical literature, just in general. 18 Q. Is Exhibit No. 2 a complete electronic file 19 of the information that you've been provided and 20 reviewed in connection with your opinions in the 21 case? 22 A. It's as complete as I am aware. 23 Q. Okay. Was there any attempt by you to 24 segregate out things from the electronic file,</p> | <p>1 BY MR. THOMAS: 2 Q. Did you give me everything you have, to the 3 best of your ability? 4 A. Everything that my understanding was that I 5 was supposed to provide you -- 6 Q. Okay. 7 A. -- is on that disc -- or that USB, from my 8 understanding. 9 Q. Are there any materials that you gathered 10 yourself or you received from others in connection 11 with your work in this case that you did not produce 12 to us? 13 A. I don't know what types of materials those 14 would be. 15 Q. As far as you know, you gave us everything 16 that you either found yourself or that others gave 17 you in connection with your work in this case? 18 A. That's my understanding. 19 Q. And for what purpose did you review the 20 depositions of Dr. Iakovlev? 21 A. Well, they sent them to me. 22 And I said that I wanted to review 23 them, because -- since he's a pathologist expert in 24 this litigation as well, I wanted to see the types</p> |
| Page 71 | Page 73 |
| <p>1 Exhibit No. 2, that you didn't produce to us? 2 MR. AYLSTOCK: Well, again, we've 3 lodged our objections to a lot of the materials in 4 there and you have those objections. 5 And you can ask the question. 6 A. I didn't catch the end of that question. 7 THE REPORTER: Do you need me to 8 repeat it? 9 THE WITNESS: Yes, please. 10 (The record was read as requested: 11 "Was there any attempt by you to 12 segregate out things from electronic 13 file, Exhibit No. 2, that you didn't 14 produce to us?"") 15 MR. CURTIS: I don't even know what 16 that means. Do you mean -- 17 MR. THOMAS: He might be able to 18 answer this question. If he can, he can answer it. 19 MR. AYLSTOCK: If you understand it, 20 Doctor. 21 MR. CURTIS: I don't get "to 22 segregate" from what? You know, are you asking -- 23 MR. THOMAS: I'll start over again. 24 ///</p> | <p>1 of questions that he was being asked. 2 And, you know, if there was something 3 that surprised me about what they were asking, or 4 something that I didn't think about that I should 5 have evaluated or -- you know, I mean, I'm -- I'm a 6 human being just like everybody else, so I can make 7 mistakes, like anybody else. 8 And I thought, well, let me see if 9 maybe he has a different understanding if he's asked 10 a question, and I think, well, okay, this is how I 11 would answer the question. 12 But then he answers it a different 13 way. And then I have to think to myself, well, this 14 is just in general. Well, am I thinking about it 15 differently or is he thinking about it differently? 16 Let me go back to the literature on 17 this point and see what the literature says. 18 So that was my intention when I -- any 19 time I've reviewed deposition transcripts from any 20 of the experts. 21 Q. And I believe you said you reviewed one or 22 two reports of Dr. Iakovlev. Correct? 23 A. Correct. 24 Q. Do you know what cases they were?</p> |

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| <p>1 A. I'm not 100 percent sure, but I believe one 2 of them maybe is Bellew or ...</p> <p>3 Q. Good. Do you recall disagreeing with 4 anything that Dr. Iakovlev said in his reports?</p> <p>5 A. Not that I can recall.</p> <p>6 Q. Do you recall disagreeing with anything 7 that Dr. Iakovlev wrote in his papers that you have?</p> <p>8 A. Again, not that I can recall.</p> <p>9 Q. Okay. Have you ever met Dr. Iakovlev?</p> <p>10 A. No.</p> <p>11 Q. Have you ever spoken to him on the phone?</p> <p>12 A. No.</p> <p>13 Q. Have you spoken with any other pathologists 14 who are looking at these types of issues in this 15 litigation?</p> <p>16 A. Not to my knowledge.</p> <p>17 Q. Are you a neuropathologist?</p> <p>18 A. I'm not board certified in neuropathology.</p> <p>19 Q. What is a neuropathologist?</p> <p>20 A. So the focus of a neuropathologist would 21 be, I would say, central nervous system issues, 22 generally, brain and spinal cord, and dealing with 23 both the non-neoplastic and neoplastic entities that 24 occur in that region.</p> | <p>1 expert reports, I can't remember who was who.</p> <p>2 Q. Okay. Would those reports be on the thumb 3 drive or the jump drive that you've given us?</p> <p>4 A. I believe so. I don't know.</p> <p>5 Q. Did you find yourself disagreeing with what 6 Dr. Vogel said?</p> <p>7 A. Well, I don't remember what -- exactly what 8 he said, but -- and I don't remember which case it 9 was in reference to.</p> <p>10 Q. Okay.</p> <p>11 A. But there were things that I remember 12 thinking that it was -- I guess, the best word would 13 be "petty."</p> <p>14 Q. What did you think was petty about 15 Dr. Vogel's report?</p> <p>16 A. I can't remember if it was his report or 17 not, but I believe it was his report that he talked 18 about a figure of mine and said something like 19 "Well, clearly his lack of experience is obvious 20 because he didn't comment on nerve in this picture." 21 Which I found to be so absurd and so petty and so 22 ridiculous that I actually laughed out loud when I 23 read it.</p> <p>24 Because any time any pathologist puts</p> |
| Page 75 | Page 77 |
| <p>1 Some of them also do muscle biopsies 2 and evaluate those, or large nerve biopsies and 3 evaluate those for pathology. I mean, that's very 4 neuropathologist-dependent because not all of them 5 do that. I would say that's basically what they do.</p> <p>6 Q. Did you consult with any neuropathologists 7 in connection with your opinions in this case?</p> <p>8 A. I didn't consult with any neuropathologists 9 with regards to this case, no.</p> <p>10 Q. Have you read any expert reports of 11 neuropathologists submitted by Ethicon?</p> <p>12 A. I believe so.</p> <p>13 Q. Which ones have you read?</p> <p>14 A. I don't recall the name. I think it was 15 Hannes Vogel.</p> <p>16 Q. The Stanford pathologist?</p> <p>17 A. I think so.</p> <p>18 Is he a neuropathologist?</p> <p>19 Q. Yes, he is.</p> <p>20 A. Yes. Then that's one of the ones that I 21 can remember.</p> <p>22 Q. Dr. McClendon?</p> <p>23 A. I recall the name. 24 I've read so many of the defense</p> | <p>1 any picture in any report, or whatever, in any 2 figure in a peer-reviewed article or a figure in a 3 text, we don't describe every single element of a 4 picture and what's in there.</p> <p>5 It's not a children's coloring book 6 that I'm, you know, have a line and say, this is the 7 hand; this is the arm.</p> <p>8 Color the hand blue; color the arm 9 white.</p> <p>10 So I found that that was -- for him to 11 point that out as evidence of my lack of experience 12 with regards to nerves, I just -- I found that 13 amusing.</p> <p>14 Q. Anything substantive about his report that 15 you disagreed with, that you recall?</p> <p>16 MR. AYLSTOCK: Objection to form. 17 We can pull out the report if that's 18 really what you're going to do, but this isn't --</p> <p>19 MR. THOMAS: I don't want to go to 20 that. I'm asking what he recalls.</p> <p>21 MR. AYLSTOCK: And, as you know, his 22 reports are case specific, so I'll remind you we 23 have limited time for this general deposition.</p> <p>24 MR. THOMAS: And you're using it right</p> |

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| <p>1 now.</p> <p>2 MR. AYLSTOCK: And you're using it,</p> <p>3 and I'm pointing that out to you --</p> <p>4 MR. THOMAS: Thank you.</p> <p>5 MR. AYLSTOCK: -- as a courtesy.</p> <p>6 MR. THOMAS: Thank you.</p> <p>7 A. So I read his whole report. And, again, I</p> <p>8 don't remember -- I read so many of them, I don't</p> <p>9 remember the details of all of them without them in</p> <p>10 front of me. And I don't --</p> <p>11 I think because that one comment about</p> <p>12 the nerve struck me as so funny that I don't</p> <p>13 remember other specifics about --</p> <p>14 MR. AYLSTOCK: And if you'd like, we</p> <p>15 can get a printout of it and give it to you.</p> <p>16 MR. THOMAS: I don't want that, Bryan.</p> <p>17 I'm just asking what he recalls.</p> <p>18 A. I would say that's what I recall, as I sit</p> <p>19 here without it.</p> <p>20 BY MR. THOMAS:</p> <p>21 Q. Are you able to determine from the</p> <p>22 histology section under "Light Microscopy" whether</p> <p>23 nerve twigs that you see are sensory, motor, or</p> <p>24 autonomic?</p> | <p>1 sensation that a nerve carries cannot</p> <p>2 be determined without identification</p> <p>3 of the sensory receptor that creates</p> <p>4 the signal?"</p> <p>5 A. I would say that sounds biologically</p> <p>6 correct.</p> <p>7 BY MR. THOMAS:</p> <p>8 Q. I'm not sure of the qualification. Why do</p> <p>9 you say "biologically correct"?</p> <p>10 A. Because you're talking about a mechanism.</p> <p>11 So that's a biologic mechanism, and so I would say</p> <p>12 that sounds biologically correct.</p> <p>13 Q. And is it fair to say that you need to</p> <p>14 identify the receptors to conclude that a given</p> <p>15 nerve fiber will transmit pain signals?</p> <p>16 A. I don't know if that's true.</p> <p>17 Q. Do you disagree with it or don't know if</p> <p>18 it's true?</p> <p>19 A. I would say that I would say that more</p> <p>20 likely than not that that's not necessarily the</p> <p>21 case.</p> <p>22 Q. Why?</p> <p>23 A. Because these nerve bundles carry, as I</p> <p>24 said, both sensory and motor signals. So I don't</p> |
| <p style="text-align: center;">Page 79</p> <p>1 A. Well, most of them have sensory and motor</p> <p>2 functions, by definition.</p> <p>3 Q. But are you able to discern from your</p> <p>4 review of the slide the extent to which there's</p> <p>5 sensory, motor, or autonomic?</p> <p>6 A. So, from reviewing just a regular H&E</p> <p>7 slide, there's no way to tell with regards to</p> <p>8 sensory and motor.</p> <p>9 Q. Or autonomic?</p> <p>10 A. Right. Autonomic.</p> <p>11 Q. Is there any stain that's capable of</p> <p>12 differentiating among nerves?</p> <p>13 A. I don't use those stains on a day-to-day</p> <p>14 basis, so that's not something that I did in this</p> <p>15 litigation or have reviewed, because I don't -- I</p> <p>16 don't do that.</p> <p>17 Q. Do you agree that the type of sensation</p> <p>18 that a nerve carries cannot be determined without</p> <p>19 identification of the sensory receptor that creates</p> <p>20 the signal?</p> <p>21 THE WITNESS: Can you repeat that?</p> <p>22 THE REPORTER: Yes.</p> <p>23 (The record was read as requested:</p> <p>24 "Do you agree that the type of</p> | <p style="text-align: center;">Page 81</p> <p>1 think that you have to say -- I don't think you have</p> <p>2 to know the receptor to know for sure what kind of</p> <p>3 signal it's carrying.</p> <p>4 Q. Do you agree that not all sensory nerve</p> <p>5 fibers transmit pain signals?</p> <p>6 A. I would say that's correct.</p> <p>7 Q. Are you suggesting by the reports that</p> <p>8 you've offered in these cases that you're able to</p> <p>9 diagnose disease by examining nerve twigs that you</p> <p>10 see in these slides?</p> <p>11 MR. AYLSTOCK: Objection to form.</p> <p>12 THE WITNESS: Could you repeat that?</p> <p>13 THE REPORTER: Yes.</p> <p>14 (The record was read as requested:</p> <p>15 "Are you suggesting by the reports</p> <p>16 that you've offered in these cases</p> <p>17 that you're able to diagnose disease</p> <p>18 by examining nerve twigs that you see</p> <p>19 in these slides?")</p> <p>20 A. I don't understand that question.</p> <p>21 BY MR. THOMAS:</p> <p>22 Q. Okay. Let me ask this question, and ask it</p> <p>23 the other way.</p> <p>24 When you look at these slides, and you</p> |

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| <p>1 identify what you do, what is your purpose for these 2 cases? What are you trying to do with what you 3 reviewed from these slides?</p> <p>4 MR. AYLSTOCK: Objection to form.</p> <p>5 A. I would say my main purpose in reviewing 6 these slides is to correlate my microscopic findings 7 with the clinical indication for the surgical 8 removal of the mesh. And to generate a pathologic 9 differential diagnosis with regards to what the 10 clinical indication was for the surgery and with 11 what I'm seeing histologically and to rule out other 12 causes that could have influenced the patient's 13 infections or pain or dyspareunia, or whatever -- 14 erosion, whatever else could have influenced that.</p> <p>15 As a pathologist, that would be my 16 main goal as to both correlate the findings that I'm 17 seeing with what's described in the medical 18 literature, as well as rule out other pathologic 19 causes for those clinical symptoms and signs.</p> <p>20 BY MR. THOMAS:</p> <p>21 Q. What does the term "correlate" mean to you?</p> <p>22 A. "Correlate" would be to take one set of 23 findings with another set of findings and relate 24 them to one another, I would say, would be a general</p> | <p>1 all of the information from the rest of the findings 2 in order to make the appropriate differential 3 diagnosis?</p> <p>4 A. Well, I mean, in addition to my slides, I 5 would -- I'm not just reviewing them in a vacuum.</p> <p>6 Q. I understand that.</p> <p>7 A. So I review -- I ask for a full set of the 8 medical records, and in some cases have asked if a 9 deposition transcript for the plaintiff has been -- 10 is available if I feel like there is any sort of 11 inconsistency in the medical record, or something 12 that isn't correlating with what the surgeon is 13 reporting. Then I will ask for additional material.</p> <p>14 But in these cases at least, I had 15 extensive medical records that were just thousands 16 and thousands of pages, so --</p> <p>17 And it seemed to me from my review to 18 be pretty complete, so as I went through them, for 19 the most part, I think there may have been a couple 20 cases where I specifically said, "Do you have this 21 report?"</p> <p>22 Or, "I don't have this operative 23 report. Did you not send that?"</p> <p>24 And, "Oh, well, actually, no. It's in</p> |
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| <p>1 definition that I would use.</p> <p>2 Q. And in your work in this case, one set of 3 findings is your findings from your review of the 4 histologic slides. Correct?</p> <p>5 A. That's correct.</p> <p>6 Q. And what is the other set of findings that 7 you're correlating with in order to give your 8 opinion in this case?</p> <p>9 A. Either the surgeon's findings operatively 10 or the patient's symptoms or signs that have been 11 described.</p> <p>12 Q. And as a result of that, you then make a 13 differential diagnosis as a pathologist as to the 14 likely cause of the symptomology. Did I understand 15 that correctly?</p> <p>16 A. Yes. I would say that's fair.</p> <p>17 Q. So you have control over the information 18 that you review. You have a limited number of 19 slides and you can look at it, and that's your set 20 of findings. Correct?</p> <p>21 A. Yes.</p> <p>22 MR. AYLSTOCK: Objection to form.</p> <p>23 BY MR. THOMAS:</p> <p>24 Q. What do you do to make sure that you have</p> | <p>1 this file folder, or maybe I missed it or 2 something."</p> <p>3 So there were times when I would call 4 and say, "You know, I can't find this. Did you 5 include this?"</p> <p>6 Or, "You know, does this plaintiff 7 have a deposition already? I'd like to review the 8 deposition in this case."</p> <p>9 Q. And all the information that you received 10 for each of these six cases is on that flash drive 11 that you supplied to us. Correct?</p> <p>12 A. Yes.</p> <p>13 MR. AYLSTOCK: Just so -- I think --</p> <p>14 MR. THOMAS: Subject to the objections 15 that you made.</p> <p>16 MR. AYLSTOCK: Well, that, and I think 17 you also have some Dropboxes that might be 18 completely coextensive or not, but some links were 19 provided last evening.</p> <p>20 MR. THOMAS: Thank you for the timely 21 production of the documents.</p> <p>22 MR. AYLSTOCK: Same goes for you in 23 every other deposition that I've been in. But I 24 appreciate the compliment.</p> |

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| <p>1 BY MR. THOMAS:</p> <p>2 Q. So what do you do to satisfy yourself that 3 you have a complete set of information with which to 4 do your differential diagnosis?</p> <p>5 MR. AYLSTOCK: Objection to form.</p> <p>6 A. Well, I'm a little uncomfortable by the 7 verbiage of that question.</p> <p>8 But -- I don't know what I do to 9 satisfy myself that I'm okay with the information, 10 but I basically review all of the -- once I have 11 reviewed all of the data, all of the medical 12 records, if I feel like I have a complete picture of 13 what was going on clinically, then that's what I'm 14 looking for.</p> <p>15 BY MR. THOMAS:</p> <p>16 Q. First of all, I don't mean to insinuate 17 anything by my question. All I'm trying to 18 understand is, at some point you become satisfied 19 that you have what information you need to make a 20 differential diagnosis.</p> <p>21 And all I want to understand is how you 22 go through that process to make sure you understand 23 that you have what you need in order to make an 24 appropriate differential diagnosis.</p> | <p>1 medical records, depositions or other information, 2 related to these individual plaintiffs for the 3 formation of your report.</p> <p>4 A. I don't know what kind of help you're 5 referring to.</p> <p>6 Q. Well, you just described to me quite a 7 volume of information. Did you do it all yourself?</p> <p>8 A. I did it all myself.</p> <p>9 Q. Okay. And for these six cases, about how 10 many hours have you spent working on these cases?</p> <p>11 A. Many, many, many hours. I don't have a 12 number off the top of my head.</p> <p>13 Q. Are your billing records included in what 14 you've produced to us?</p> <p>15 A. I'm not aware if they are or not.</p> <p>16 Q. I know --</p> <p>17 MR. AYLSTOCK: If they're not, I'll 18 get them to you, Dave.</p> <p>19 MR. THOMAS: Okay.</p> <p>20 BY MR. THOMAS:</p> <p>21 Q. How do you keep your time?</p> <p>22 A. I have on my computer Word documents for 23 each of the cases. And when I'm reviewing 24 something, I have it on my drive -- my Google Drive.</p> |
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| <p>1 A. Okay.</p> <p>2 Q. That's all I intend with the question.</p> <p>3 A. Okay.</p> <p>4 MR. AYLSTOCK: And I think he's 5 answered that extensively in what he's already said, 6 so ...</p> <p>7 MR. THOMAS: All I want to do is make 8 sure he didn't think I was disparaging him in any 9 way.</p> <p>10 A. Oh, no.</p> <p>11 BY MR. THOMAS:</p> <p>12 Q. Do you rely on counsel to supply you with 13 the information that you need?</p> <p>14 MR. AYLSTOCK: With regard to the 15 medical --</p> <p>16 BY MR. THOMAS:</p> <p>17 Q. With respect to the individual plaintiffs.</p> <p>18 A. Well, yes. I don't contact the -- their -- 19 it's not like I ask for a list of their physicians 20 and contact the offices directly.</p> <p>21 Q. Okay.</p> <p>22 A. I rely on them to be responsive when I ask 23 for medical records and further information.</p> <p>24 Q. Did you have any help in reviewing the</p> | <p>1 so if I'm in a library or wherever, at home, I look 2 at what time I start and then when I'm done, I add 3 that time.</p> <p>4 Q. Okay. So real time as you're doing work, 5 you update your individual time sheet for each case. 6 Is that fair?</p> <p>7 A. Constantly, yes.</p> <p>8 Q. All right. And you have on your computer 9 right now your up-to-date time that you spent on 10 each of these six cases?</p> <p>11 A. Yes.</p> <p>12 Q. Do you maintain any other separate bill in 13 addition to the six cases for which you're appearing 14 here today for any general work you're doing on the 15 file?</p> <p>16 A. I think I have in the past, yes.</p> <p>17 Q. Okay. So if I wanted to review the time 18 that you spent on this matter, this litigation, it 19 would be these six individual times, and then a 20 general file or a general bill that would provide 21 time that you spent there. Fair?</p> <p>22 A. Yes. But having said that, I would also 23 say that within the specific cases, there are times 24 when I'm reviewing general information that relates</p> |

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| <p>1 to that particular case.</p> <p>2 Q. Absolutely understand that.</p> <p>3 A. Okay.</p> <p>4 Q. Is there any other category of time for</p> <p>5 which you submit bills to the plaintiffs?</p> <p>6 A. I don't think there's any other category of</p> <p>7 time that I submitted a bill.</p> <p>8 Q. So if I get the bills for the six cases and</p> <p>9 the general file, I'll have a complete set of the</p> <p>10 bills and time that you've submitted to the</p> <p>11 plaintiffs in the case?</p> <p>12 A. Yes.</p> <p>13 Q. When you record your time as you do it, you</p> <p>14 record it by the amount of time you spent. Correct?</p> <p>15 A. Correct.</p> <p>16 Q. Do you describe what you were doing?</p> <p>17 A. Yes.</p> <p>18 Q. And what is your purpose when you describe</p> <p>19 what you're doing? What are you trying to say?</p> <p>20 A. For my own recollection, mainly. It hasn't</p> <p>21 come up yet, maybe because it's not case specific.</p> <p>22 But a lot of times I will be asked in</p> <p>23 depositions in the past, "When were you first</p> <p>24 contacted by the attorneys?"</p> | <p>1 MR. AYLSTOCK: Objection to form.</p> <p>2 A. I think I would leave as far as the actual</p> <p>3 material that needs to be used for these surgical</p> <p>4 procedures more to a surgeon.</p> <p>5 I would say as a pathologist with</p> <p>6 regards to what type of material they should use --</p> <p>7 whether it's synthetic, absorbable, nonabsorbable,</p> <p>8 biologic -- I would say I don't really have a</p> <p>9 general opinion about what is best surgically to use</p> <p>10 on these patients.</p> <p>11 BY MR. THOMAS:</p> <p>12 Q. Does that apply to both stress urinary</p> <p>13 incontinence and pelvic organ prolapse?</p> <p>14 A. I would say yes, in general.</p> <p>15 Q. Just so I can shut this down:</p> <p>16 Is it fair to understand that you will</p> <p>17 not give any opinions at the trial in this case about</p> <p>18 the appropriate mesh material for the treatment of</p> <p>19 stress urinary incontinence or pelvic organ prolapse?</p> <p>20 MR. CURTIS: Object to the form of the</p> <p>21 question. That's not what you asked him before.</p> <p>22 MR. THOMAS: Sure, it is.</p> <p>23 MR. CURTIS: You're talking about</p> <p>24 absorbable mesh and then you generalized and</p> |
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| <p>1 And I'll go to my invoice and say,</p> <p>2 this -- on such-and-such day, I had a ten-minute</p> <p>3 conversation with so-and-so.</p> <p>4 And then "Well, when did you receive</p> <p>5 the slides?"</p> <p>6 "Well, on such-and-such a day I</p> <p>7 received the slides and did an inventory."</p> <p>8 So I do it for completeness' sake and</p> <p>9 to be able to give a good timeline if I'm asked.</p> <p>10 Q. Okay. So the purpose of your time charges</p> <p>11 is not only to count your time but also to give you</p> <p>12 chronology so that you can recall what work you did</p> <p>13 at what time?</p> <p>14 A. I'd say that's correct.</p> <p>15 Q. In Exhibit No. 3, you discuss generally the</p> <p>16 concept or the idea of absorbable mesh on the first</p> <p>17 couple pages --</p> <p>18 A. Okay.</p> <p>19 Q. -- do you remember that? Under "Comment"</p> <p>20 on page 2.</p> <p>21 A. Yes.</p> <p>22 Q. Do you have any opinions that absorbable</p> <p>23 mesh should be used for the treatment of stress</p> <p>24 urinary incontinence?</p> | <p>1 expanded the scope of it.</p> <p>2 MR. THOMAS: He just -- I don't have</p> <p>3 real time. I'm sorry.</p> <p>4 THE REPORTER: Do you want his last</p> <p>5 answer?</p> <p>6 MR. THOMAS: I do.</p> <p>7 "I think I would leave as far as the</p> <p>8 actual material that needs to be used for these</p> <p>9 surgical procedures more to a surgeon.</p> <p>10 I would say as a pathologist with</p> <p>11 regards to what type of material they should use,</p> <p>12 whether it's synthetic, absorbable, nonabsorbable,</p> <p>13 biologic, I would say I don't really have a general</p> <p>14 opinion about what is best surgically to use on these</p> <p>15 patients."</p> <p>16 BY MR. THOMAS:</p> <p>17 Q. And my question is, is it fair to</p> <p>18 understand that you're not going to give an opinion</p> <p>19 at trial in these cases about what material</p> <p>20 manufacturers should use in mesh for the treatment</p> <p>21 of stress urinary incontinence or pelvic organ</p> <p>22 prolapse in women?</p> <p>23 MR. AYLSTOCK: Do you mean as opposed</p> <p>24 to the materials implanted in these women in the</p> |

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| | <p>1 Ethicon mesh?</p> <p>2 MR. THOMAS: That's what I'm trying to 3 understand, Bryan. He told me no.</p> <p>4 MR. AYLSTOCK: I'm trying to 5 understand too. I'm not telling him not to answer, 6 I'm just trying to understand what you're getting 7 at.</p> <p>8 A. So, I guess, to clarify, my opinion would 9 be, as a pathologist, I'm not going to tell a 10 surgeon, for this particular patient you need to use 11 this material; for that patient you should use that 12 material.</p> <p>13 Oh, you need to make sure and go 14 suburethrally with this type of material; go through 15 the obturator foramen with this type of material.</p> <p>16 That's not my goal or purview, I 17 guess, as a pathologist. Mine would be to evaluate 18 the types of material that I see pathologically and 19 to correlate whatever histopathologic responses I'm 20 seeing to whatever material with what's going on 21 clinically.</p> <p>22 BY MR. THOMAS:</p> <p>23 Q. Do you have an opinion to offer in this 24 case that the manufacturers should have used</p> | <p>1 seen pathologically in this specimen, if there was 2 another specimen type or another mesh type that was 3 known to have these -- these characteristics that 4 would not have given you the same -- that would 5 likely not have given you the same pathologic 6 response, would I feel, as a pathologist, that this 7 type of material was better than another type of 8 material? I would just answer any question as it's 9 posed to me.</p> <p>10 I don't know -- you know, when I'm 11 asked, am I going to give this type of opinion in a 12 court, I don't -- all I can say is I'm going to 13 answer whatever questions I'm allowed to answer in a 14 court, based on -- if I feel, based on my 15 information that I have in the medical literature 16 and what I've reviewed, that I can answer the 17 question.</p> <p>18 BY MR. THOMAS:</p> <p>19 Q. For any of the six cases that you've 20 reviewed and that we're here for the next two days, 21 is there a different material that you would 22 advocate for use of the treatment of stress urinary 23 incontinence that would not produce the symptoms 24 that these women experienced?</p> |
| | <p style="text-align: center;">Page 95</p> <p>1 different material in any of the meshes you've 2 analyzed?</p> <p>3 A. I don't know about the specific types of 4 material that was available to them. I didn't have 5 those internal documents that I recall that 6 specifically mention the different types of material 7 that they could have used or how they advertised 8 those materials. I don't have any of that 9 information.</p> <p>10 Q. I understand that.</p> <p>11 Is it fair to understand that you're 12 not prepared at trial to offer an opinion that 13 Ethicon should have used a particular material in 14 the -- in its meshes used for the treatment of stress 15 urinary incontinence or pelvic organ prolapse?</p> <p>16 MR. AYLSTOCK: Objection to form.</p> <p>17 MR. CURTIS: Yes.</p> <p>18 A. Well, you know, as a pathologist, the way I 19 deal with -- or I guess, as any physician, the way I 20 deal with questions that are medically related would 21 be to answer the question that is posed to me.</p> <p>22 So, I guess, with respect to your 23 question, if I was asked at trial as a pathologist 24 and in my opinion with the types of responses I've</p> | <p style="text-align: center;">Page 97</p> <p>1 A. Again, I don't -- I didn't discuss any use 2 of a material that should have been used in contrast 3 to what was used.</p> <p>4 Q. Okay. And, as you sit here today, you 5 don't have any opinions in that regard?</p> <p>6 A. I haven't been asked any specific questions 7 regarding that, and I haven't reviewed material with 8 respect to that subject.</p> <p>9 Q. Okay. Do you agree that it's a normal 10 histological finding to see nerve branches in all 11 types of surgically removed tissues?</p> <p>12 MR. AYLSTOCK: Objection to form.</p> <p>13 A. Could you repeat that, please?</p> <p>14 BY MR. THOMAS:</p> <p>15 Q. Do you agree that it is a normal 16 histological finding to see nerve branches in all 17 types of surgically removed tissues?</p> <p>18 A. No.</p> <p>19 Q. Why don't you agree with that?</p> <p>20 A. Because it's not correct; that's why.</p> <p>21 Q. Okay. Do you agree that surgical 22 interruption of the microscopic nerve supply to all 23 types of soft tissues in the human anatomy, whether 24 in the presence of artificial materials or not, is</p> |

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| <p>1 always accompanied by fibrosis and the repair of 2 blood vessels, nerve fibers, and other vital 3 connective tissues?</p> <p>4 MR. AYLSTOCK: Objection to form.</p> <p>5 A. I would not say always with respect to any 6 physiologic property in the body. But I would say 7 that, more likely than not, different degrees of 8 stromal reaction occur following those types of 9 surgical procedures.</p> <p>10 BY MR. THOMAS:</p> <p>11 Q. Okay. What is the mechanism between, you 12 know, inflammation that you describe in your reports 13 and pain?</p> <p>14 A. I would say the mechanism with regards to 15 inflammation and pain is something that is extremely 16 complex and not something that I, as a pathologist 17 generally would report or describe.</p> <p>18 Simply correlating the fact that 19 inflammation is known to be associated with pain and 20 reporting whether that inflammation is present or 21 not, but not with regards to the receptors and the 22 cytokines that are produced and the feedback loops 23 and the cycles. That's not something that I have 24 specifically reviewed in preparation for this.</p> | <p>1 Neutrophils have different cytokines 2 that can be secreted, and those can actually 3 interact with the sensory receptors on the nerve 4 itself which can give you a different quality of 5 pain.</p> <p>6 So when I say it's complex, it's 7 because there's different types of pain and there's 8 different types of inflammatory reactions that can 9 produce those different types of pain.</p> <p>10 BY MR. THOMAS:</p> <p>11 Q. Finished?</p> <p>12 A. Um-hmm.</p> <p>13 Q. Thank you.</p> <p>14 MR. THOMAS: Let's go back to his 15 prior answer, please.</p> <p>16 (Pause in proceedings.)</p> <p>17 BY MR. THOMAS:</p> <p>18 Q. I understood your prior answer to be that 19 generally, you -- as a pathologist, you would not 20 generally describe the mechanism of pain -- 21 mechanism between inflammation and pain. Is that 22 fair?</p> <p>23 A. In a report.</p> <p>24 Q. Okay. Is there a discipline within -- in</p> |
| <p style="text-align: center;">Page 99</p> <p>1 Q. Is it fair to understand that you can't 2 tell me today the mechanism between inflammation and 3 pain?</p> <p>4 MR. AYLSTOCK: Objection to form.</p> <p>5 A. No. I'm not saying -- what I said is that 6 that mechanism is complex. And that --</p> <p>7 BY MR. THOMAS:</p> <p>8 Q. Can you explain it to me?</p> <p>9 MR. AYLSTOCK: In how many hours?</p> <p>10 A. Well, it's not -- it's that there --</p> <p>11 Inflammation, depending on the 12 inflammatory cell, whether it's a macrophage or a 13 neutrophil, secretes different kinds of interlukens 14 and cytokines, and those can cause other cells to 15 migrate to the area. Those can induce fibroblasts 16 proliferation, which in a more end stage, may entrap 17 a nerve and cause pain that way.</p> <p>18 Alternatively, if you have an 19 eosinophil, which is another type of inflammatory 20 cell, that secretes, say, Interleukin-5 or 21 Interleukin-6 that can cause vasodilation of the 22 vessels and cause edema to rush out into the tissue 23 which gives you a pressure sensation which is 24 painful.</p> | <p style="text-align: center;">Page 101</p> <p>1 medicine that is the appropriate discipline to 2 discuss the specifics of the mechanism of 3 inflammation and pain.</p> <p>4 MR. AYLSTOCK: Objection to form.</p> <p>5 A. I don't think that there's a specific 6 discipline or specialty where that's their focus.</p> <p>7 BY MR. THOMAS:</p> <p>8 Q. Is there a discipline within medicine that 9 has its focus that is more specialized than your own 10 in this area?</p> <p>11 MR. AYLSTOCK: In what area?</p> <p>12 BY MR. THOMAS:</p> <p>13 Q. In the mechanism between inflammation and 14 pain.</p> <p>15 THE WITNESS: Can you repeat that?</p> <p>16 MR. THOMAS: I'll just ask it again.</p> <p>17 THE WITNESS: Okay.</p> <p>18 BY MR. THOMAS:</p> <p>19 Q. Is there an area of medicine that is more 20 specialized than your areas of expertise to explain 21 the mechanism between inflammation and pain?</p> <p>22 A. Well, I don't know if it would be in 23 medicine or in biology. Because everything that I 24 described is, you know, biological processes, which</p> |

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| <p>1 can occur in humans and animals. 2 So I would say that it's not 3 necessarily in human medicine where any specialties 4 focus on specifically inflammation and pain and 5 those mechanisms that are causing them.</p> <p>6 Q. Is it your testimony that you're as 7 qualified in your discipline as any other discipline 8 to offer opinions of the mechanism of inflammation 9 and pain?</p> <p>10 MR. AYLSTOCK: Objection to form.</p> <p>11 A. I don't know.</p> <p>12 BY MR. THOMAS:</p> <p>13 Q. Okay. In your research in this case, did 14 you make any effort to determine the existence of 15 any studies that looked at the role of inflammation 16 in mesh explants for patients who had mesh removed 17 because of pain, as opposed to mesh removed for 18 reasons other than pain?</p> <p>19 THE WITNESS: Can you repeat that?</p> <p>20 THE REPORTER: Yes.</p> <p>21 (The record was read as requested: 22 "In your research in this case, did 23 you make any effort to determine the 24 existence of any studies that looked</p> | <p>1 Q. So you chose not to deal with it. 2 A. No. I dealt with in the sense of I read it 3 and I evaluated it. But from my recollection, there 4 were a lot of problems with it.</p> <p>5 Q. Okay. Do you remember generally what the 6 problems were?</p> <p>7 A. I think that it was -- I think it was a 8 retrospective study, and I didn't feel like they -- 9 it didn't seem like they could confidentially rule 10 out that the patients that they were saying didn't 11 have pain didn't actually have pain, because they 12 were reviewing the records -- the medical records 13 only, and there was no attempt to actually discuss 14 these patients' reported pain or not, or had -- 15 I should say had pain and just weren't 16 reporting it because maybe they were so focused on 17 their -- I think, it was urinary symptoms, which was 18 the other group that had, like, urinary symptoms and 19 supposedly not pain.</p> <p>20 But I mean, I know patients in general 21 will go to a physician and have several problems and 22 report really one of them, and they may have another 23 problem. But unless they are specifically asked may 24 not report it. So that was one issue with the</p> |
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| <p>1 at the role of inflammation in mesh 2 explants for patients who had mesh 3 removed because of pain as opposed to 4 mesh removed for reasons other than 5 pain?"</p> <p>6 MR. CURTIS: Object to the form of the 7 of the question.</p> <p>8 A. Yes. I did.</p> <p>9 BY MR. THOMAS:</p> <p>10 Q. Okay. Did you find any studies?</p> <p>11 A. Yeah. There was a study that -- there was 12 one study in particular that I reviewed. I can't 13 remember the author's last name. I think it might 14 have been Hill, or ...</p> <p>15 Q. Yep.</p> <p>16 That's not on your reliance list. Is 17 there a reason why?</p> <p>18 A. I tried to include everything on my 19 reliance list that I had reviewed.</p> <p>20 You know, again, not everything that's 21 on there -- or not everything that is -- forms my 22 opinions is on there, it just is the nature of my 23 profession. But on this particular study, I thought 24 that it was a really bad study.</p> | <p>1 study. 2 Another one is they didn't really 3 characterize the type of fibrosis or inflammation. 4 They talked about grading it, like 0 to 3 or 0 to 2, 5 I don't -- I know there were several different 6 categories.</p> <p>7 But they didn't really describe that 8 in detail, like -- and the association with the 9 mesh, whether that was inflammation around the mesh 10 or it was away from the mesh.</p> <p>11 And the reason that's important is 12 because the specimens that would have been reviewed 13 that were from around the bladder or around the 14 urethra, that tissue, in general, can have some 15 degree of inflammation that maybe would just be 16 normal for that region, or could be normal for that 17 region.</p> <p>18 So if someone's not having pain, and 19 they're saying, Oh, well, look, the patients that 20 had no pain had just as much inflammation as the 21 patients that had pain.</p> <p>22 Well, you're not taking into account 23 the fact that the patients that didn't have pain, 24 their specimens were from areas that normally would</p> |

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| <p>1 have had more inflammatory cells, which is skewing 2 the data. That was another problem that I had with 3 that.</p> <p>4 Just off the top of my head, those are 5 the ones that I can remember.</p> <p>6 Q. Sure. Any other studies that you looked at 7 analyzing the role of inflammation in meshes 8 explanted for reasons of pain and meshes explanted 9 for non-pain reasons that you've looked at but 10 haven't included in your report or your reliance 11 list?</p> <p>12 A. There may have been others. I just can't 13 remember the specifics of the authors or the actual 14 names.</p> <p>15 Q. You agree that less than 5 percent of 16 patients undergoing explantation of SUI slings do so 17 for long-term pain, don't you?</p> <p>18 MR. AYLSTOCK: Objection to form.</p> <p>19 A. Would you repeat that?</p> <p>20 BY MR. THOMAS:</p> <p>21 Q. Do you agree of the patients who are 22 undergoing -- well, strike that.</p> <p>23 (Pause in proceedings.)</p> <p>24 //</p> | <p>1 percentage of complications -- the percentage of 2 patients who receive mesh for stress urinary 3 incontinence that experience mesh for -- pain for 4 longer than six months?</p> <p>5 MR. AYLSTOCK: Objection to form.</p> <p>6 A. Again, I think that that's a very confusing 7 question for me.</p> <p>8 I don't really understand if you're 9 asking from post-op day number one until post-op day 10 number 180, or if they have six months of pain that 11 may be on and off over the course of several years? 12 I guess I just don't understand.</p> <p>13 BY MR. THOMAS:</p> <p>14 Q. That's fine.</p> <p>15 You do agree that for more than 16 90 percent of the patients who receive mesh for the 17 treatment of stress urinary incontinence they have no 18 complaints of pain after six months?</p> <p>19 MR. AYLSTOCK: Objection to form.</p> <p>20 What kind of pain?</p> <p>21 A. I -- I don't know. I don't understand.</p> <p>22 BY MR. THOMAS:</p> <p>23 Q. Have you studied the issue of pain as a 24 complication in the use of mesh for the treatment of</p> |
| <p style="text-align: center;">Page 107</p> <p>1 BY MR. THOMAS:</p> <p>2 Q. For patients who receive mesh implants for 3 treatment of SUI, do you know what percentage 4 experience complications of pain more than six 5 months?</p> <p>6 MR. AYLSTOCK: Objection to form.</p> <p>7 A. I guess I don't understand if you're asking 8 pain greater than six months in duration or --</p> <p>9 BY MR. THOMAS:</p> <p>10 Q. Yes.</p> <p>11 A. -- after six months.</p> <p>12 Q. Six months greater in duration.</p> <p>13 MR. AYLSTOCK: From the time of the 14 original implant?</p> <p>15 MR. THOMAS: Yes.</p> <p>16 A. I don't understand.</p> <p>17 So starting at six months and then 18 have it for six months?</p> <p>19 BY MR. THOMAS:</p> <p>20 Q. No.</p> <p>21 At the time of implant, pain persists 22 from date of implant to longer than six months.</p> <p>23 A. So --</p> <p>24 Q. Are you aware of the number -- the</p> | <p style="text-align: center;">Page 109</p> <p>1 stress urinary incontinence?</p> <p>2 MR. AYLSTOCK: Objection. Asked and 3 answered. He's already --</p> <p>4 MR. THOMAS: Please let me ask the 5 questions completely, Bryan.</p> <p>6 MR. AYLSTOCK: I objected to it.</p> <p>7 A. Could you repeat that?</p> <p>8 BY MR. THOMAS:</p> <p>9 Q. Have you studied the extent to which pain 10 is a complication in patients who receive mesh for 11 the treatment of stress urinary incontinence?</p> <p>12 A. Yes. I've reviewed the different 13 complications from mesh.</p> <p>14 Q. What are the rates of complications for 15 pain over six months in women who've received mesh 16 for the treatment of stress urinary incontinence?</p> <p>17 MR. AYLSTOCK: Objection to form.</p> <p>18 A. I don't know if you're talking about -- I 19 don't specifically remember reading about studies 20 that have looked at patients that have had six 21 months of continual pain from the time of their 22 surgery until six months post-op. I don't recall 23 reading that data.</p> <p>24 ///</p> |

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| <p>1 BY MR. THOMAS:</p> <p>2 Q. Okay. And to the extent that you looked at 3 studies in that regard, they'd be on Exhibit 2?</p> <p>4 A. They should be.</p> <p>5 Q. Okay. Do all women who receive mesh for 6 the treatment of stress urinary incontinence have an 7 inflammatory response to that mesh?</p> <p>8 MR. AYLSTOCK: Objection to form.</p> <p>9 A. I would say all women that have synthetic 10 mesh implanted would have an inflammatory response 11 to mesh.</p> <p>12 BY MR. THOMAS:</p> <p>13 Q. Why do some women experience pain and 14 others do not?</p> <p>15 A. I would say every human is different and 16 there's a reason why complication rates aren't 17 0 percent versus 100 percent. It's because every 18 body is different, every body has different 19 responses, different genetics.</p> <p>20 Maybe some people have a higher 21 genetic predisposition to having a particular type 22 of cytokine that's released.</p> <p>23 Maybe some patients have other medical 24 issues that would influence pain versus not pain.</p> | <p>1 discuss that issue specifically insofar as relates to 2 the replacement of mesh for the treatment of stress 3 urinary incontinence?</p> <p>4 MR. AYLSTOCK: Objection to form.</p> <p>5 A. I would have to go through my articles. I 6 don't remember the specifics of your question in 7 relationship to one particular article, but I would 8 have to look at my different articles that I've 9 reviewed.</p> <p>10 BY MR. THOMAS:</p> <p>11 Q. Okay. Fair to understand you don't recall 12 one now?</p> <p>13 A. I can't recall any of the specifics now, 14 no.</p> <p>15 Q. Is it true that chronic inflammation is a 16 finding seen in the vaginal tissues of women 17 suffering from stress urinary incontinence, pelvic 18 organ prolapse, and other pelvic floor dysfunction 19 even before mesh is implanted?</p> <p>20 MR. AYLSTOCK: Objection to form.</p> <p>21 A. I don't think that that's necessarily true, 22 no.</p> <p>23 BY MR. THOMAS:</p> <p>24 Q. Okay. So --</p> |
| <p style="text-align: center;">Page 111</p> <p>1 That doesn't take away from the fact that they're 2 experiencing pain from a mesh.</p> <p>3 So all of these factors influence 4 whether someone has a particular type of 5 symptomatology following any type of surgery.</p> <p>6 Q. Did you review any studies analyzing the 7 question why some women who receive mesh for the 8 treatment of SUI, and who have inflammation, have 9 pain and others do not?</p> <p>10 A. Could you repeat that?</p> <p>11 Q. Did you review any studies or papers of any 12 kind which analyzed the question of why some women 13 who receive mesh for the treatment of SUI experience 14 pain and others do not?</p> <p>15 A. Well, the first time you said 16 "inflammation".</p> <p>17 Q. What did I say the second time?</p> <p>18 A. You didn't say "inflammation" the second 19 time.</p> <p>20 Q. Well, let me start over again.</p> <p>21 What I'm trying to understand, Doctor, 22 very simply: You gave me a descriptive answer about 23 why some people experience pain and others don't. 24 Are you aware of any papers that</p> | <p style="text-align: center;">Page 113</p> <p>1 A. And it depends on the anatomic location.</p> <p>2 Q. So if a woman has SUI, stress urinary 3 incontinence, you would not necessarily expect to 4 see inflammation if you did histology in the area of 5 the SUI?</p> <p>6 A. In what area of the SUI? 7 In the urethra? in the bladder? in the 8 vagina?</p> <p>9 There's a whole -- it's a completely 10 different histology for all these locations.</p> <p>11 Q. Are you saying there won't be any 12 inflammation in some of these people who have these 13 pelvic floor disorders?</p> <p>14 A. Yeah. I would say if you took a vaginal 15 biopsy in someone with SUI, I don't see why you 16 would have inflammation.</p> <p>17 Q. Okay.</p> <p>18 A. If it wasn't otherwise inflamed by some 19 other reason.</p> <p>20 Q. Do you agree with this statement: 21 "At present, general human tissue 22 interactions with the mesh are known, but we have an 23 incomplete understanding of interactions specific to 24 a mesh material and design as well as the</p> |

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| <p>1 pathophysiology of any complications"?</p> <p>2 A. I don't understand that question.</p> <p>3 MR. AYLSTOCK: Objection to form.</p> <p>4 A. Or that statement. That seems very</p> <p>5 convoluted to me.</p> <p>6 BY MR. THOMAS:</p> <p>7 Q. Okay.</p> <p>8 A. I'm not sure who wrote it for you but could</p> <p>9 you reread it.</p> <p>10 Q. I didn't write it for me. But nobody wrote</p> <p>11 it for me.</p> <p>12 "At present, general human tissue</p> <p>13 interactions with the mesh are known, but we have an</p> <p>14 incomplete understanding of interactions specific to</p> <p>15 a mesh material and design, as well as the</p> <p>16 pathophysiology of any complications."</p> <p>17 A. I would say none of these processes are</p> <p>18 completely known 100 percent. There's always things</p> <p>19 that are discovered about the specific mechanisms of</p> <p>20 all these interactions. But that doesn't take away</p> <p>21 from the fact that we know a significant amount --</p> <p>22 at least enough to know how certain material, like</p> <p>23 mesh, would interact in a patient's body.</p> <p>24 Q. Do you agree with this statement:</p> | <p>1 amount of time, it would degrade. But I -- it would</p> <p>2 be something that you would have to evaluate</p> <p>3 microscopically.</p> <p>4 MR. THOMAS: Let's go off the record</p> <p>5 for a second.</p> <p>6 (Recess from 10:42 a.m. to 10:51 a.m.)</p> <p>7 BY MR. THOMAS:</p> <p>8 Q. Can you approximate how much time you've</p> <p>9 spent working on this litigation from the time you</p> <p>10 were retained till now?</p> <p>11 A. Maybe -- I would say approximately 200</p> <p>12 hours. Probably not -- maybe not that much. I</p> <p>13 don't know. 160 hours.</p> <p>14 Q. And that would be for the six cases, as</p> <p>15 well as the general file for which you've billed</p> <p>16 time?</p> <p>17 A. Correct.</p> <p>18 Q. All right. And you charge \$500 for your</p> <p>19 time?</p> <p>20 A. Yes.</p> <p>21 Q. And have you submitted bills yet?</p> <p>22 A. Some.</p> <p>23 Q. Have you been paid?</p> <p>24 A. Some.</p> |
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| <p>1 "That the question of whether</p> <p>2 polypropylene degrades in vivo has not been fully</p> <p>3 resolved despite decades of use"?</p> <p>4 MR. AYLSTOCK: Objection to form.</p> <p>5 A. Repeat that.</p> <p>6 BY MR. THOMAS:</p> <p>7 Q. The question of whether polypropylene</p> <p>8 degrades in vivo has not been fully resolved despite</p> <p>9 decades of use.</p> <p>10 MR. AYLSTOCK: Same objection.</p> <p>11 A. The polypropylene doesn't completely</p> <p>12 dissolve?</p> <p>13 BY MR. THOMAS:</p> <p>14 Q. Do you agree with the statement as I've</p> <p>15 read it?</p> <p>16 A. Read it again.</p> <p>17 Q. The question of whether polypropylene</p> <p>18 degrades in vivo has not been fully resolved despite</p> <p>19 decades of use.</p> <p>20 MR. AYLSTOCK: Same objection.</p> <p>21 A. I guess I don't know, because I would say</p> <p>22 it depends on the time. Because if it's -- maybe</p> <p>23 not fully with respect to maybe everyone, but I</p> <p>24 would say more likely than not after a significant</p> | <p>1 MR. THOMAS: Pay his bills, Bryan.</p> <p>2 MR. AYLSTOCK: You know, you keep me</p> <p>3 busy.</p> <p>4 BY MR. THOMAS:</p> <p>5 Q. And when -- what's your best recollection</p> <p>6 of when you were hired in this case?</p> <p>7 A. I think there were some initial contact in</p> <p>8 January of this year, but I didn't receive slides or</p> <p>9 anything until well after that.</p> <p>10 Because I know my reports were due in</p> <p>11 early May, and maybe I had slides for over a month</p> <p>12 before that or something.</p> <p>13 Q. When did you begin your general literature</p> <p>14 review?</p> <p>15 A. Probably in February, I would imagine.</p> <p>16 January, February.</p> <p>17 Q. That would be reflected in your time</p> <p>18 charges?</p> <p>19 A. It should be.</p> <p>20 Q. Do you have privileges at hospitals now?</p> <p>21 A. Yes.</p> <p>22 Q. And which hospitals do you have privileges</p> <p>23 now?</p> <p>24 A. Let's see. St. Davids Medical Center.</p> |

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| <p>1 Q. St. David's?</p> <p>2 A. Yes.</p> <p>3 Seton Medical Center.</p> <p>4 Q. Seton?</p> <p>5 A. S-e-t-o-n.</p> <p>6 It's all in the second paragraph of</p> <p>7 my ...</p> <p>8 Q. It sure is.</p> <p>9 Dell Children's Medical Center?</p> <p>10 A. Um-hmm.</p> <p>11 Q. Arise Austin Medical Center?</p> <p>12 A. Arise (pronouncing), yeah.</p> <p>13 Q. Westlake Medical Center?</p> <p>14 A. Yes.</p> <p>15 Q. Resolute Health Hospital?</p> <p>16 A. Right. Seton Northwest.</p> <p>17 Q. As a result of your work in this case, have</p> <p>18 you developed any concerns medically about the safe</p> <p>19 use of Prolene polypropylene in patients?</p> <p>20 MR. AYLSTOCK: Objection to form.</p> <p>21 A. I would say not from a pathologist's</p> <p>22 standpoint in my -- in my perspective, I guess, or</p> <p>23 from my perspective.</p> <p>24 ///</p> | <p>1 work that I'm doing as an expert witness that I have</p> <p>2 felt the need to go to the medical staff and say</p> <p>3 this has to never be used again.</p> <p>4 BY MR. THOMAS:</p> <p>5 Q. I need to ask the question a little more</p> <p>6 specifically.</p> <p>7 A. Okay.</p> <p>8 Q. Is it fair to understand that nothing in</p> <p>9 the work that you've done has caused you to believe</p> <p>10 that the use of Prolene sutures at the hospitals</p> <p>11 where you have privileges creates a danger in the</p> <p>12 people that receive those Prolene sutures?</p> <p>13 MR. AYLSTOCK: Objection to form.</p> <p>14 A. I would say from my standpoint, that's</p> <p>15 correct.</p> <p>16 BY MR. THOMAS:</p> <p>17 Q. Is it fair to understand that nothing that</p> <p>18 you've done in the work you've done in this case</p> <p>19 caused you to believe that the use of</p> <p>20 Prolene polypropylene in the mesh used in the</p> <p>21 treatment of stress urinary incontinence creates a</p> <p>22 danger to any of the women that received those</p> <p>23 meshes at the hospitals where you have privileges?</p> <p>24 MR. AYLSTOCK: Let me object to the</p> |
| <p style="text-align: center;">Page 119</p> <p>1 BY MR. THOMAS:</p> <p>2 Q. As a doctor who has medical privileges at</p> <p>3 the doctors -- at the hospitals that you've</p> <p>4 identified on your report, have you developed any</p> <p>5 concern about the safe use of Prolene polypropylene</p> <p>6 in patients of those hospitals?</p> <p>7 A. Well, I would say that's not really --</p> <p>8 there is nothing that I have identified that I find</p> <p>9 to be influencing mortality or something that would</p> <p>10 be a significant alarm that I would raise with the</p> <p>11 medical staff.</p> <p>12 Q. If you had identified any concern from your</p> <p>13 work in this case that you believe that</p> <p>14 PROLENE Polypropylene could not safely be used in</p> <p>15 patients at these hospitals, you would tell the</p> <p>16 medical staff, wouldn't you?</p> <p>17 MR. AYLSTOCK: Let me object to the</p> <p>18 form.</p> <p>19 As you know, Dave, a lot of this is</p> <p>20 off the market, so your question is entirely too</p> <p>21 broad.</p> <p>22 A. Again, I -- from what I have experienced in</p> <p>23 my practice, there is nothing that I am seeing in my</p> <p>24 practice that I guess would relate to the current</p> | <p style="text-align: center;">Page 121</p> <p>1 word "danger." I don't know what you mean by that.</p> <p>2 A. Well, again, as I said, there's nothing</p> <p>3 that I would say is life threatening that would</p> <p>4 necessitate me as a pathologist, in my role at the</p> <p>5 hospitals, going to the medical staff to ensure that</p> <p>6 something is not used.</p> <p>7 BY MR. THOMAS:</p> <p>8 Q. Do you find from your work in this case</p> <p>9 that Prolene polypropylene and the meshes used for</p> <p>10 the treatment of stress urinary incontinence</p> <p>11 manufactured by Ethicon create an unreasonable risk</p> <p>12 of danger to women that receive them in the</p> <p>13 hospitals where you have privileges?</p> <p>14 MR. AYLSTOCK: Objection to form.</p> <p>15 THE WITNESS: Could you repeat that?</p> <p>16 (The record was read as requested:</p> <p>17 "Do you find from your work in this</p> <p>18 case that Prolene polypropylene and</p> <p>19 the meshes used for the treatment of</p> <p>20 stress urinary incontinence</p> <p>21 manufactured by Ethicon create an</p> <p>22 unreasonable risk of danger to women</p> <p>23 that receive them in the hospitals</p> <p>24 where you have privileges?")</p> |

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| <p>1 MR. AYLSTOCK: Same objection. 2 At what point in time? With what 3 labels affixed? It's entirely too vague. 4 A. I guess I don't really -- I don't really 5 understand the question. 6 BY MR. THOMAS: 7 Q. Is it true that you've not told anybody at 8 the hospitals where you work that they should stop 9 implanting Ethicon TVT meshes for the treatment of 10 stress urinary incontinence? True? 11 A. That's correct. 12 Q. And the reason why you haven't done that is 13 because you don't see that any of the Ethicon meshes 14 used for the treatment of stress urinary 15 incontinence present an unreasonable risk of harm to 16 the women that receive them. Correct? 17 MR. AYLSTOCK: Objection to form. 18 A. No. I would say that's kind of an 19 oversimplification of my role as a pathologist in 20 the hospital. 21 My role would not be to alert the 22 medical staff to stop using a particular type of 23 medical device without knowing if there are risks 24 that are now discussed with these patients may be</p> | <p>1 preoperative visits. 2 BY MR. THOMAS: 3 Q. Fair to conclude, though, that you have not 4 had conversations with anybody on the medical staffs 5 of any of the hospitals where you have privileges 6 about any risks associated with the TVT devices for 7 the treatment of stress urinary incontinence. 8 Correct? 9 MR. AYLSTOCK: Objection to form. 10 A. I have not had any discussions with the 11 medical staff about TVT or any sort of 12 polypropylene-containing mesh. 13 MR. THOMAS: Okay. I think we're 14 ready to go to individual cases. 15 MR. AYLSTOCK: Okay. 16 MR. THOMAS: Do you want to take a 17 break first? 18 MR. AYLSTOCK: Yeah. Let's conclude 19 the general deposition. 20 MR. THOMAS: And just for the record, 21 we have an agreement that background questions and 22 questions that we've asked in this general 23 deposition will be applied to the individual cases 24 so that we don't have to reask or redo certain</p> |
| <p style="text-align: center;">Page 123</p> <p>1 what I consider to be dangerous, maybe a woman now 2 after discussing those known risks with her 3 physician wouldn't consider dangerous. 4 I would say my role as a pathologist 5 would be that if I found that these were associated 6 with a high risk of developing leukemia, and it's 7 not something that's reported in the medical 8 literature, and it's a product that's still being 9 used. 10 Something like that at that point, I 11 would go and sound the alarm to the medical staff 12 that, Hey, this is something that is not described 13 in their handouts. It's not something that's being 14 discussed by the company. You haven't had the 15 opportunity to discuss this risk with the patient. 16 But my experience as a pathologist from reviewing X 17 number of patients is that this is causing leukemia 18 so you need to be aware of that. 19 There's no scenario like that that has 20 occurred that I have felt the need to alert the 21 medical staff, because the risk/benefit ratio of any 22 procedure, whether I deem it dangerous or not, is 23 not my responsibility given that that's what the 24 surgeon discusses with the patients in their</p> | <p style="text-align: center;">Page 125</p> <p>1 things. 2 MR. AYLSTOCK: Yeah. In fact, we'll 3 insist that it not be reasked or redone. 4 MR. THOMAS: Right. 5 MR. AYLSTOCK: Anything that was 6 covered in the general portions of this report. 7 MR. THOMAS: But there will be times 8 obviously where we will have to ask predicate 9 questions in order to form an appropriate question, 10 and we'll deal with those as they arise. 11 MR. AYLSTOCK: Mr. Curtis will deal 12 with them. 13 MR. CURTIS: Well, the understanding 14 is, the time we've just spent is on the general 15 issues, and will not be repeated in the six 16 individual cases. 17 MR. THOMAS: Well, as best we can, 18 unless we have to relate it to a question in order 19 to make the question clear. And we'll figure that 20 out. I don't think we'll have any problem with 21 that. 22 MR. CURTIS: I don't think we will 23 either. 24 What's the time?</p> |

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| <p>1 THE REPORTER: The total time is 2 2 hours, 36 minutes. 3 4 MR. CURTIS: Thank you. 5 (Proceedings concluded at 11:03 a.m.) 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24</p> | <p>1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 PAUL J. MICHAELS, M.D. DATE 16 17 18 Subscribed and sworn 19 to before me this 20 _____ day of _____, 20_____. My commission expires: _____ 21 22 Notary Public 23 24</p> |
| <p>Page 127</p> <p>1 - - - - - 2 ER R A T A 3 - - - - - 4 PAGE LINE CHANGE 5 _____ 6 REASON: _____ 7 _____ 8 REASON: _____ 9 _____ 10 REASON: _____ 11 _____ 12 REASON: _____ 13 _____ 14 REASON: _____ 15 _____ 16 REASON: _____ 17 _____ 18 REASON: _____ 19 _____ 20 REASON: _____ 21 _____ 22 REASON: _____ 23 _____ 24 REASON: _____</p> | <p>Page 129</p> <p>1 IN THE UNITED STATES DISTRICT COURT 2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA 3 CHARLESTON DIVISION 4 _____ 5 IN RE: ETHICON, INC., PELVIC) Master File No. REPAIR SYSTEM PRODUCTS) 6 PRODUCTS LIABILITY LITIGATION) 2:12-MD-02327) 7 THIS DOCUMENT RELATES TO THE) MDL 2327 FOLLOWING CASES IN WAVE 2) 8 OF MDL 200:) JOSEPH R. GOODWIN Tamara Carter, et al. v.) Ethicon, Inc., et al.) U.S. DISTRICT JUDGE 10 Civil Action No. 2:12-cv-01661) Sandra Childress, et al. v.) Ethicon, Inc., et al.) 12 Civil Action No. 2:12-cv-01564) Marion Chrysler v.) Ethicon, Inc., et al.) 14 Civil Action No. 2:12-cv-02060) Melissa Sanders, et al. v.) Ethicon, Inc., et al.) 16 Civil Action No. 2:12-cv-01562) Ana Sierra, et al. v.) Ethicon, Inc., et al.) 18 Civil Action No. 2:12-cv-01819) Toni Hernandez v.) Ethicon, Inc., et al.) 20 Civil Action No. 2:12-cv-02073) REPORTER'S CERTIFICATE ORAL DEPOSITION OF PAUL J. MICHAELS, M.D. June 18, 2016</p> |

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| <p style="text-align: right;">Page 130</p> <p>1 2 I, Rebecca J. Callow, Registered Merit 3 Reporter and Notary Public in and for the State of 4 Texas, hereby certify to the following: 5 That the witness, PAUL J. MICHAELS, M.D., 6 was duly sworn by the officer and that the 7 transcript of the oral deposition is a true record 8 of the testimony given by the witness; 9 That the original deposition was delivered 10 to _____. 11 That a copy of this certificate was served 12 on all parties and/or the witness shown herein on 13 _____. 14 That pursuant to information given to the 15 deposition officer at the time said testimony was 16 taken, the following the amount of time used by 17 each party at the time of the deposition: 18 David B. Thomas (2h36m) 19 Attorney for Johnson & Johnson and 20 Ethicon, Inc. 21 Bryan F. Aylstock (0h0m) 22 Attorney for Plaintiffs 23 24</p> | <p style="text-align: right;">Page 132</p> <p>1 2 3 SUBSCRIBED AND SWORN TO under my hand and 4 seal of office on this the _____ day of 5 _____, _____. 6 7 8 Rebecca J. Callow, RMR, CRR, RPR 9 Notary Public, Travis County, Texas 10 My Commission No. 12955701-3 11 Expires: 09/12/2017 12 13 14 15 16 17 18 19 20 21 22 23 24</p> |
| <p style="text-align: right;">Page 131</p> <p>1 I further certify that pursuant to FRCP 2 Rule 30(f)(1) that the signature of the deponent: 3 [] was requested by the deponent or a 4 party before the completion of the deposition and is 5 to be returned within 30 days from date of receipt 6 of the transcript. If returned, the attached 7 Changes and Signature Page contains any changes and 8 the reasons therefor; 9 [] was not requested by the deponent or 10 a party before the completion of the deposition. 11 12 I further certify that I am neither 13 counsel for, related to, nor employed by any of the 14 parties or attorneys to the action in which this 15 proceeding was taken. Further, I am not a relative 16 or employee of any attorney of record in this cause, 17 nor am I financially or otherwise interested in the 18 outcome of the action. 19 20 21 22 23 24</p> | |